EXHIBIT A

UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR WARMING DEVICES PRODUCTS LIABILITY LITIGATION

MDL No 15-2666 (JNE/FLN)

AFFIDAVIT OF SCOTT D. AUGUSTINE MD

This Document Relates to: All Actions

- My name is Scott D. Augustine MD. I am Chief Executive Officer of the various entities subject
 to the discovery served by 3M. In this Affidavit, I shall refer both to myself and to the various
 Augustine entities as "Augustine" or "we."
- I hereby swear that the facts contained herein are within my personal knowledge (except when stated as being on information and belief or in reliance of information from another person) and are true and correct.
- 3. I have prepared this sworn statement in response to Item No. 4 in the November 23, 2016
 Order by the Honorable Franklin L. Noel regarding the relationships between me and the
 Augustine companies (jointly "Augustine") and the Kennedy Hodges law firm. Although I am
 unable to supply precise dates, I will do the best that I can.
- 4. I believe that the attorney-client relationship between Augustine and Kennedy Hodges began in 2009. As J. Randall Benham, Augustine's general counsel, stated in an affidavit filed with the Court in the Walton/Johnson discovery dispute, I cannot be precise as to the date.
 Mr. Benham has informed me, however, that Kennedy Hodges represented to the Houston

CASE 0:15-md-02666-JNE-DTS Doc. 185-1 Filed 01/19/17 Page 3 of 224 federal court in Walton that the relationship began on July 6, 2009. As far as I know, that date is correct, and I do not dispute it. The purposes of the representation were multiple, and are described below.

- 5. First, we wanted to learn about product liability litigation—how cases were analyzed, what evidence was required, etc. Neither Mr. Benham nor I have experience in this area of the law. My initial thought was that hospitals or Medicare or even states (like the tobacco litigation) might sue Bair Hugger for the massive extra costs to the system from the infections created by the pathogen-filled waste hot air. We wanted to consider any legal theories, whether brought on behalf of Augustine or others, including claims based on the Lanham Act, that would hold Bair Hugger responsible for that harm it had caused.
- Second, we wanted to understand why personal injury firms virtually never filed cases on behalf of patients injured by surgical infections.
- Finally, we wanted to educate Kennedy Hodges about the research regarding the risks of forced-air warming, receive analysis and reactions from them, and understand their concerns and objections, if any.
- 8. The relationship continued in this vein for several years. Fairly quickly, however, Kennedy Hodges expressed an interest in pursuing litigation against forced-air warming companies on behalf of patients—particularly orthopedic patients—who had suffered serious infections from the devices. We agreed that I (supported by Augustine employees) would be a nontestifying expert, helping Kennedy Hodges understand the research, the pathology of surgical infections, the patient-warming industry, the history of Bair Hugger, my efforts to educate the owners of Bair Hugger about the risks of forced air; I would occasionally review documents and provide whatever other information Kennedy Hodges might require. I did not request payment for these efforts because they were consistent with my two goals: to

CASE 0:15-md-02666-JNE-DTS Doc. 185-1 Filed 01/19/17 Page 4 of 224 stop Bair Hugger (which I invented) from injuring more patients and to promote the use of HotDog patient warming, the air-free patient-warming device that I invented as an alternative to Bair Hugger. While I cannot be precise as to the date I began my role as a non-testifying expert, I believe that it was considerably before Kennedy Hodges filed the Walton case in Texas.

- 9. As a non-testifying expert and/or client I met once or twice with Kennedy Hodges and spoke with them occasionally by phone. To the best of my knowledge, Mr. Benham conducted all written communications with Kennedy Hodges on my behalf.
- 10. I have never formally terminated the attorney-client relationship with Kennedy Hodges, and I have never received notice from Kennedy Hodges that the relationship has been terminated. I have been informed by Mr. Benham, however, that it has been several years since Kennedy Hodges has performed any legal services for Augustine.
- 11. I have also never been informed by Kennedy Hodges that I am no longer a non-testifying expert in the Walton case or any of the other cases in which Kennedy Hodges is involved. Mr. Benham has advised me, however, that at some point Kennedy Hodges "de-designated" me as such an expert. I do not know when this occurred.

FURTHER AFFIANT SAYETH NOT

Scott D. Augustine MD

December 12, 2016

EXHIBIT B



Patient Warming:

Anesthesia's Role in Orthopedic Infection Reduction

Scott Augustine, MD

CEO, Augustine Temperature Management LLC

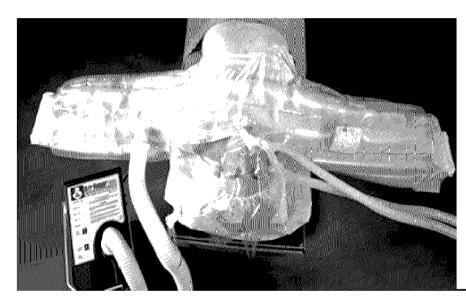
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Disclosure Statement of Financial Interest

I, Scott Augustine, do have financial interest/arrangement or affiliation with one or more organizations that may be perceived as an apparent conflict of interest in the context of the subject of this presentation; these include:

Affiliation/Financial Interest	Name of Organization
Owner	Augustine Temperature Management
Equity Position	

Conflict of Interest Disclosure





Bair Hugger® Warming

Augustine Medical Inc.
Arizant/3M

1000 watts, 40 CFM air

HotDog® Patient Warming

Augustine Temperature Management LLC.

200 watts, 0 °CFM air

Learning Objectives

This presentation will enable participants to:

- 1. Understand the benefits of patient warming in preventing soft tissue infections.
- 2. Understand the difference between soft-tissue infections and periprosthetic joint infections.
- 3. Understand the consequences of periprosthetic joint infections.
- 4. Understand the CDC warning: Do not use *αny* equipment that blows air in the OR.

Learning Objectives

- 5. Understand how operating room ventilation is designed to prevent bacteria from rising from the floor and contaminating the surgical field.
- Understand how convection currents of waste forced-air warming heat disrupt OR ventilation airflow, contaminating the sterile surgical field and increasing the risk of PJI.

Periprosthetic joint infections and how anesthesia equipment is causing them.

5

Importance of Patient Warming

- Warm patients do better than cold patients!
- The benefits of patient warming include:
 - Reduced wound infections (soft tissue)
 - Reduced blood loss
 - Reduced cardiac events
 - Lower mortality rates
 - Shortened hospital stays
- Active warming is now the "standard" set by:
 Medicare, SCIP, PQRS (US), NICE (UK)

Common Patient Warming Methods

- Water-based systems
 - History
- Forced-Air Warming (FAW)
 - Soon to be history
- Electric warming
 - The future

Normothermia's Role in Preventing SSIs (Soft-Tissue Infections)

- Kurz et al reported a 66% reduction in wound infections during colon surgery, when the patients were warmed to normothermia with FAW (compared to 2°C hypothermic, non-warmed control patients). NEJM
- Warm patients have fewer soft tissue infections.
- Corroborated by Melling (breast and hernia)

Different Kinds of Infections "SSI" vs. "PJI"

- Common mistake: lumping the varieties of infection together—causes confusion
- The term "SSI" is reserved for <u>soft-tissue</u> infections
- SSI must be differentiated from Periprosthetic joint infections ("PJI")* that can occur after total joint replacement surgery

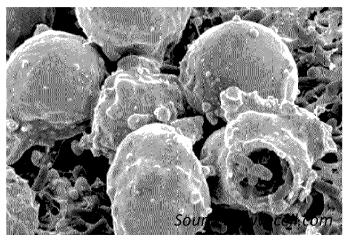
*Also known as Deep Joint Infections ("DJI")

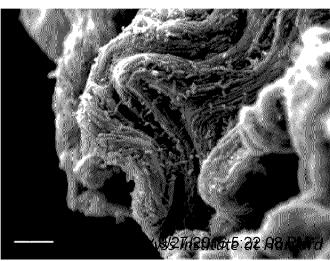
The Infectious Process

- Implanted foreign materials fundamentally change the pathophysiology of the infectious process:
 - An inoculum of more than one million bacteria are required to cause an SSI.⁷
 - A *single* bacterium can cause a PJI, and it usually enters the wound as *airborne* contamination.⁸⁻¹⁰

How can 1 germ cause a PJI?

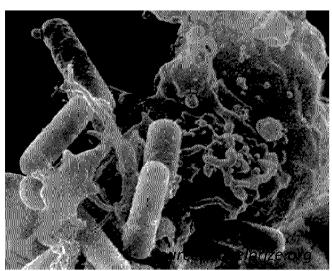
- It's all about biofilm. 11
- In the presence of an implanted foreign material, the bacterium produces a coating of exopolysaccharide material.
- Biofilm effectively protects it from antibodies and antibiotics.





No Biofilm in Soft-Tissue

- In contrast, bacteria cannot produce effective biofilm in soft tissue.
- Exposed to both antibodies and antibiotics.
- Since it takes more than a million bacteria to cause a soft tissue SSI, the airborne contamination in the operating room is virtually irrelevant for soft tissue SSIs.



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SSI vs PJI

- SSI generally an easily treatable complication
- PJI is a catastrophic complication:
 - Often requires explantation of the joint and weeks of antibiotics.
 - Patients never regain full capacity and frequently cannot accomplish the activities of daily living.
 - 12% of patients rate their life after surviving a PJI as "worse than death."

Periprosthetic joint infections (PJI)

 PJI after total joint replacement: Relatively common complication (1-2%).

- Medicare says 2% in primary hips and knees.
- → 20,000 per year in the US.

SSI vs PJI -- cost

- SSI: generally cheap to treat
- PJI: a very expensive complication:
 - Costs \$100,000 \$150,000 each.
 - Not reimbursed by Medicare.





Periprosthetic joint infections due to anesthesia equipment

- Why PJI at an anesthesia conference?
- Evidence to date: The unintended consequence of my invention (FAW) is that it may be causing 75% or more of PJIs.
- PJI is the most common serious <u>anesthetic</u> complication?

CDC warns against blowing air in the OR!

- The CDC "steals my thunder"
- "Nothing that blows air should be in an operating theater, if possible." and "...it is important not to blow air in the operating theater."69
- "Until more detailed evidence is available regarding this issue...devices that generate drafts should be banned from the operating room."

CDC warns against blowing air in the OR!

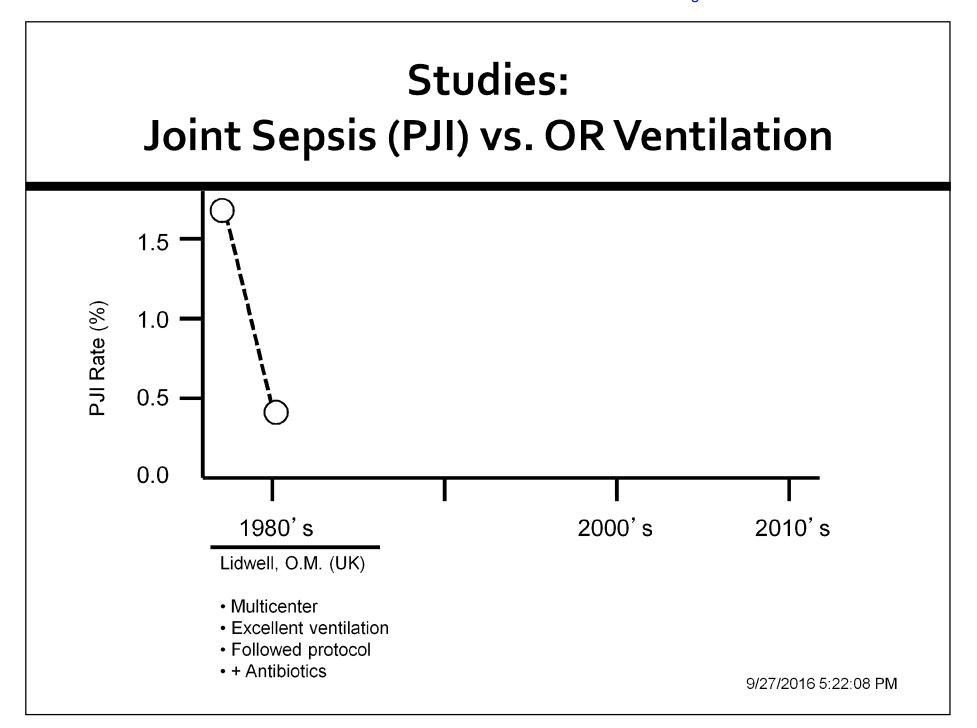
- Investigation of *Mycobαcterium* heart valve infections
- Mycobacterium contaminates aerosolized in the air blowing from Heater-Cooler Devices (genetic link)
- "Nothing that blows air should be in an operating theater, if possible." 69
- Warning against blowing air is clearly not limited to HCDs
- Forced-air warming: the worst offender of all air-blowing equipment in any operating room

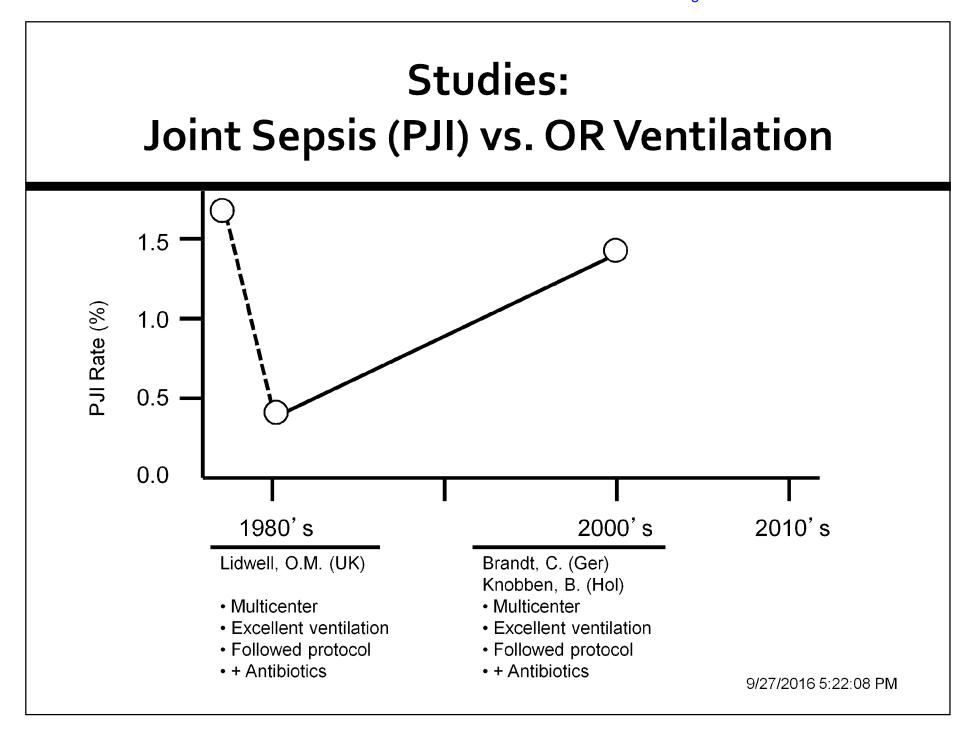
FAW blowers identical to HCDs

- 3 studies: bacteria and mold aerosolized from FAW blowers^{34,35,68}
- Bair Hugger filters 63.8% efficient (vs. HEPA 99.97%)
- Reed: 100% of blowers internally contaminated34
 - Aerosolizing 300 million bacteria-sized particles per hour
 - Emitted particle count 40x greater than the intake count = bacteria and mold were *grown inside* the blower and aerosolized
- Hamilton: blower bacteria cultured from the skin of 10% of patients⁶⁸

CDC warns against blowing air in the OR!

- CDC warning is to healthcare <u>providers</u>:
 - Unequivocally establishes that blowing air is an unacceptable risk until proven otherwise
 - "Burden of Proof" shifts from the change agent (must prove *risk*) to the healthcare providers (must prove *sαfety*)
- Providers choosing to ignore the CDC warning:
 - Must first prove FAW safety in order to avoid liability (Burden of Proof is shifted to you the provider)
 - Should disclose the CDC warning to your patients during informed consent (that will be an interesting conversation!)
- ZERO outcome studies showing FAW safety in orthopedics
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Why the increase in infection rates in these ventilation studies?

- The increase in the infection rate is despite substantial air quality efforts:
 - Laminar flow ventilation: Improved
 - Body evacuation suits: Regularly used
 - Traffic: Limited number and movement of OR personnel.
 - → → Something in the standard operating protocols must be disrupting the ventilation.

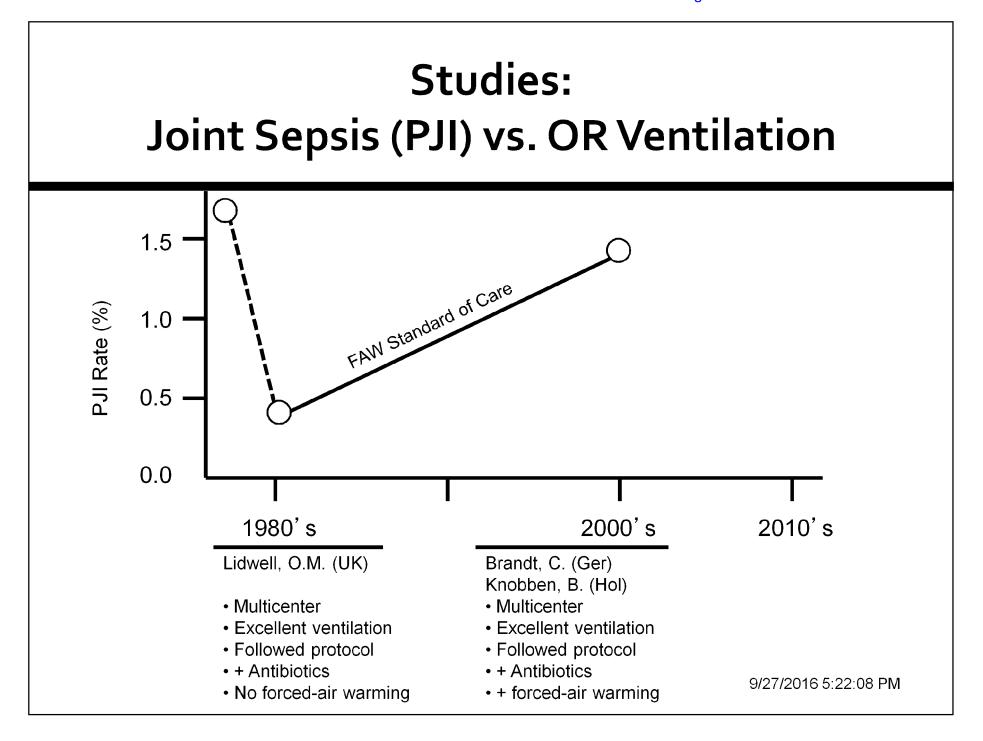
To put this in perspective, the increase in infection rates over the last 20 years has occurred despite substantial efforts to improve the air quality in orthopedic surgery. These air quality efforts commonly include: Improved laminar flow ventilation, regular use of body evacuation suits or "space suits", and limiting the of movement and number of OR personnel. Given all of these efforts, one would think infection rates would be dropping. Why are they actually getting worse? Let's test a hypothesis: Maybe we don't actually have the ultra-clean ventilation we think we have.

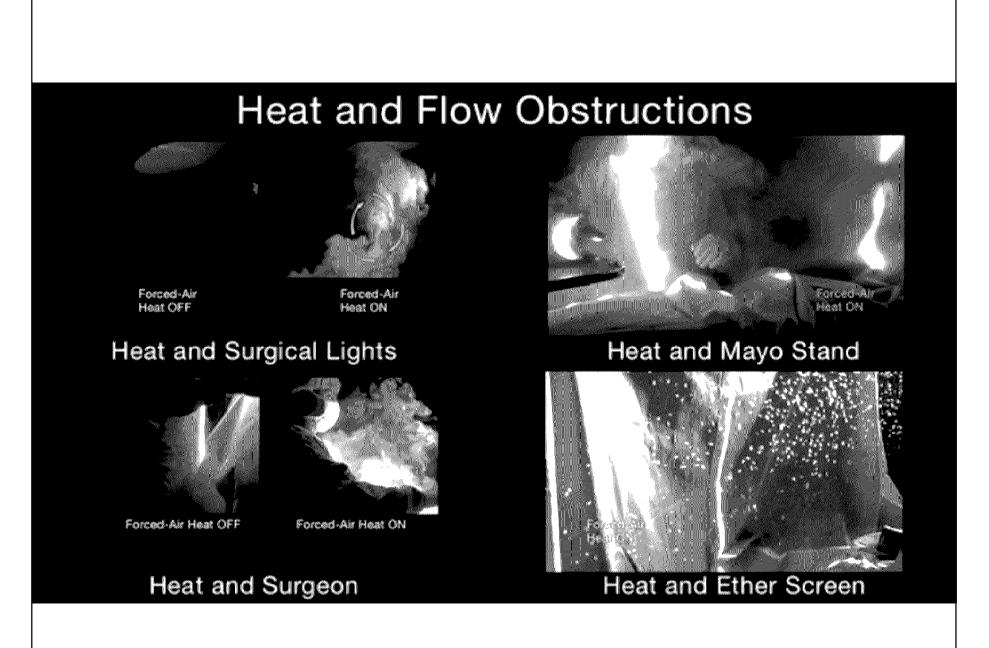
US Operating Room Ventilation Standards

- ASHRAE Standard 170: ceiling-to-floor, clean-todirty:
 - 1. Section 7.1.1.a: "Design of the ventilation system shall provide air movement that is generally from clean to less clean areas."
 - 1. Section 7.4.1.a: "The airflow shall be unidirectional, downwards..."
 - 1. Ventilation must be filtered at an efficiency of >90% for the removal of germ sized particles

Causes of ventilation disruption

- Ventilation obstructions (e.g.: surgical lights) -- same
- Personnel movement more limited
- Blowing air
 - Any new sources of blowing air introduced to the OR between the late '80's and 2000's? FAW (40-50 CFM)
- Heat (creates convection currents of rising air)
 - Any new sources of heat introduced to the OR between the late '80's and 2000's?
 - FAW! 1000 watts of waste heat vented near the floor since 1989.





Research

• Video evidence supported by 7 published studies^{44-48, 65, 67}

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* ARTHROPLASTY

Forced-air warming and ultra-clean ventilation do not mix

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Legg, A.J.; Hammer, A.J. Forced-air patient warming blankets disrupt unidirectional airflow. *B&JJ*, March 2013 vol. 95-B no. 3 407-410

 2,000 times more contaminant particles were found in the air over the wound with FAW than with air-free conductive warming.

217,400% Increase!

Warming scenario	Concentration (particles/m ³)
Control	2000
Radiant warming	1000
Forced-air warming	2 174 000

Belani, K; et al. Patient Warming Excess Heat: Effects on Orthopedic Operating Room Ventilation Performance. *A&A*. 2013 Aug;117(2):406-11

• "... exhaust from forced-air warming generated hot-air convection currents that mobilized 'bubbles' over the anesthesia drape and into the surgical site."

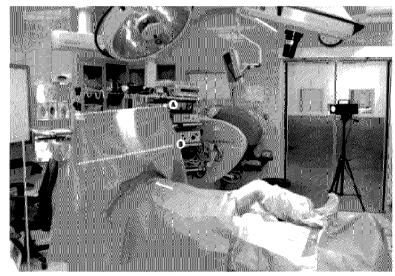
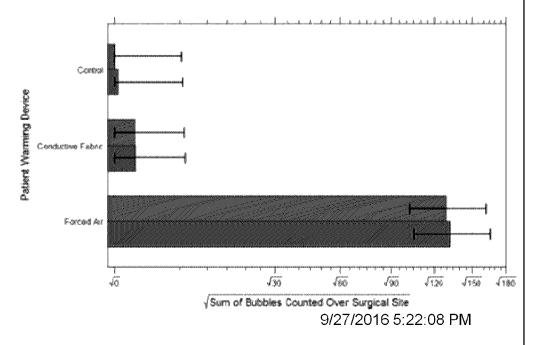
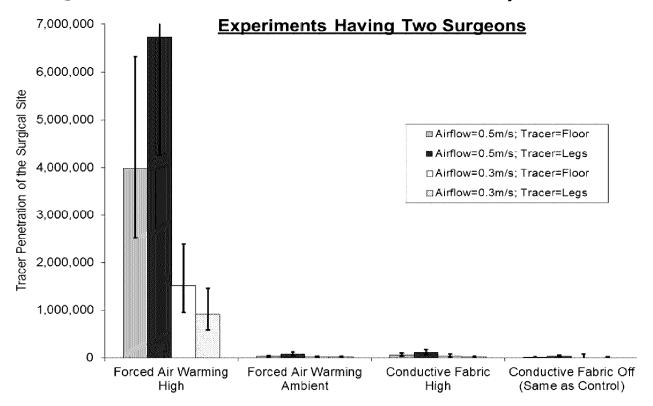


Figure 1. Total knee replacement setup showing high anesthesia drape position (A) and low anesthesia drape position (B).



Increased ventilation velocity increased contamination

• 0.3 vs 0.5 meters/sec. laminar flow velocity



Reed M, McGovern P et al. FAW vs. CFW – An evaluation of <u>laminar</u> operating room ventilation disruption. (Unpublished) 9/27/2016 5:22:08 PM

"Infection control hazards associated with the use of forced-air warming in operating theatres" --- J Hospital Infection, 2014 66

- SSI experts including DJ Leaper, Chair SSI Comm. (NICE)
 - "Many studies suggest that disruption of ultra-clean ventilation air flow by FAW is significant..."
 - "We conclude that FAW does contaminate ultra-clean ventilation..."
 - "...we recommend that surgeons should at least consider alternative patient-warming systems in areas where contamination of the operative field may be critical."

FAW Contaminates the Sterile Surgical Field

- Undisputable: Waste FAW heat rises mobilizing infectious contaminates from the floor up into the sterile surgical field. 44-49, 63-66
 - "Gotcha" response: "The heat may cause contamination, but prove to me that it causes infections!"
 - The "burden of proof" has shifted with the CDC warning, the provider must now prove safety—prove that the contamination does not cause infections.
 - Even if FAW is never proven to cause infections, how can anyone justify willfully contaminating the sterile surgical field?

Contaminated air = increased infection risk

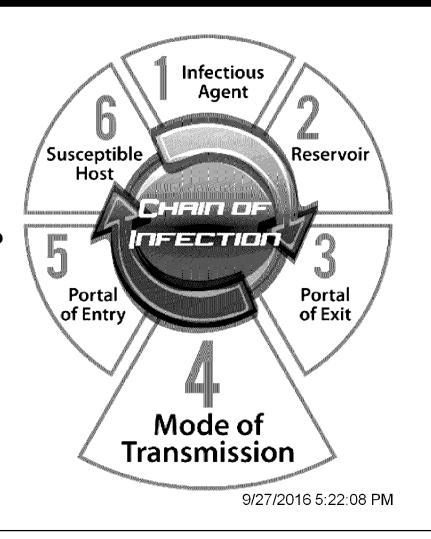
- Basic logic (If A=B and B=C then A=C)
- A. Waste FAW heat rises mobilizing infectious contaminates from the floor up into the sterile surgical field. 44-49, 63, 64, 65
- B. The concentration of airborne contaminates correlates directly with the concentration of contaminates in the wound. 2-4,51-57
- C. Concentration of contaminates in the wound correlates with the risk of PJI. (only need one bacterium) 8-10
- A=C, therefore FAW logically increases PJI risk

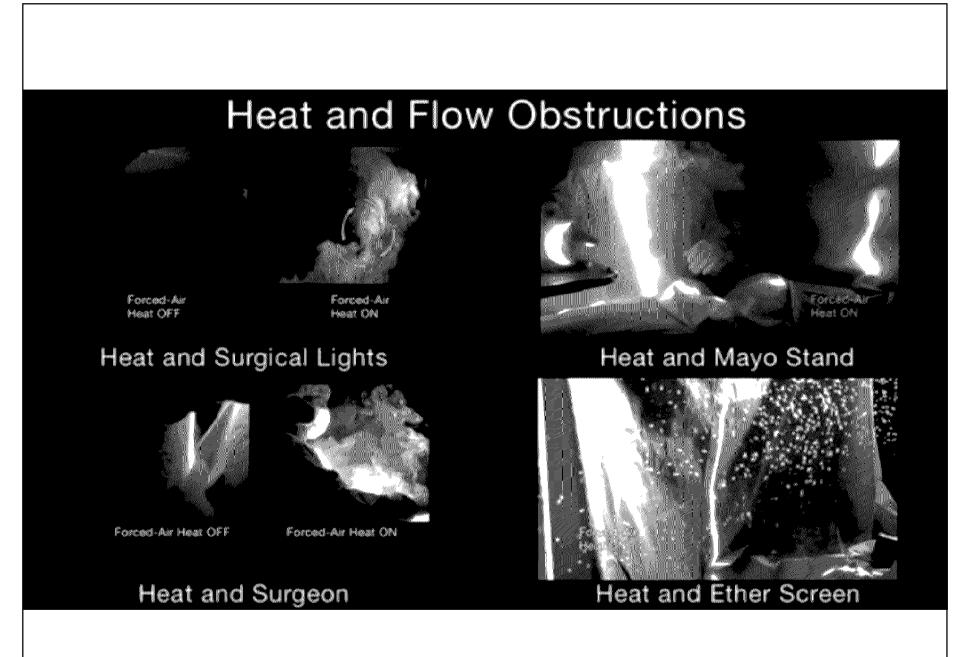
CDC: Chain of Infection

- The <u>Chain of Infection</u> is a well-known model used to understand the etiology of infections.¹³
- Each link in the chain must be present to prove the source of an infection.
- PJI: 5 of the 6 links have been proven for decades

PJI Chain of Infection: Mode of Transmission

- The missing link in the Deep Joint Chain of Infection: How do bacteria from near the floor get into the wound?
- Answer: Riding the rising waste FAW heat.





Research Results: McGovern et al. Journal of Bone and Joint Surgery-br 44

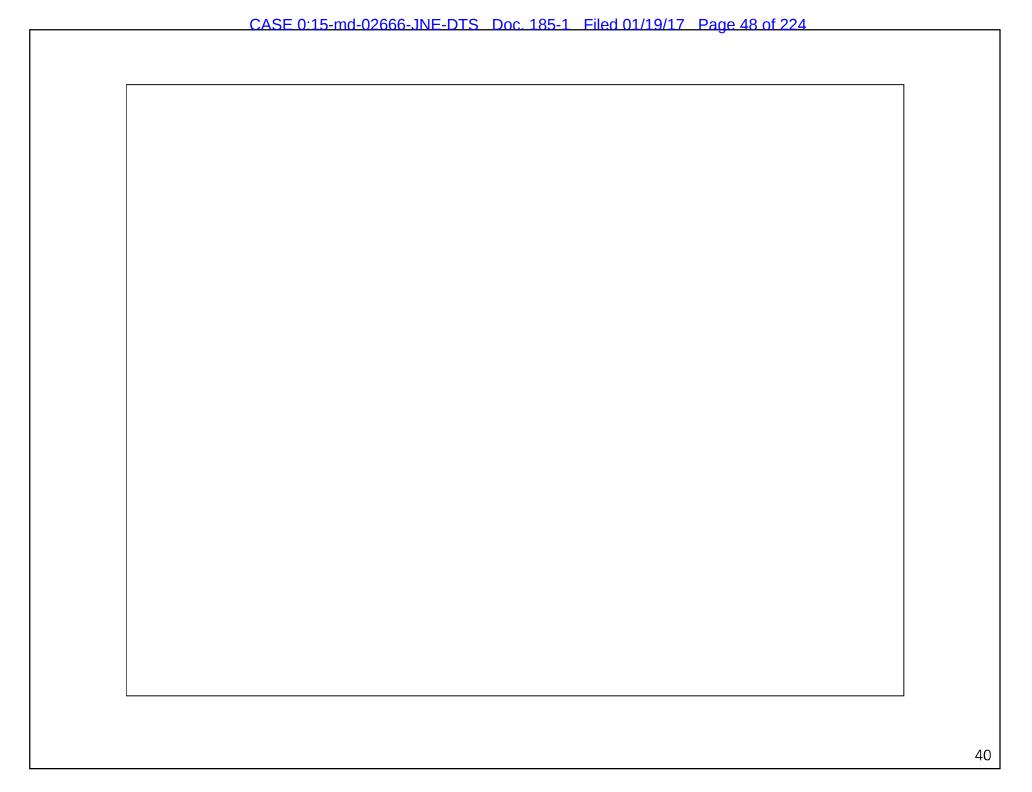
- Discontinued FAW and switched to HotDog airfree warming in total joint replacement surgery.
- "[Forced-air] Patient warming ventilation disruption was associated with a significant increase in deep joint infections, as demonstrated by an elevated infection odds ratio (3.8, p=0.028) for the forced air versus conductive fabric patient groups (n=1437 cases, 2.5-year period)."

Research Results: McGovern et al. Journal of Bone and Joint Surgery-br

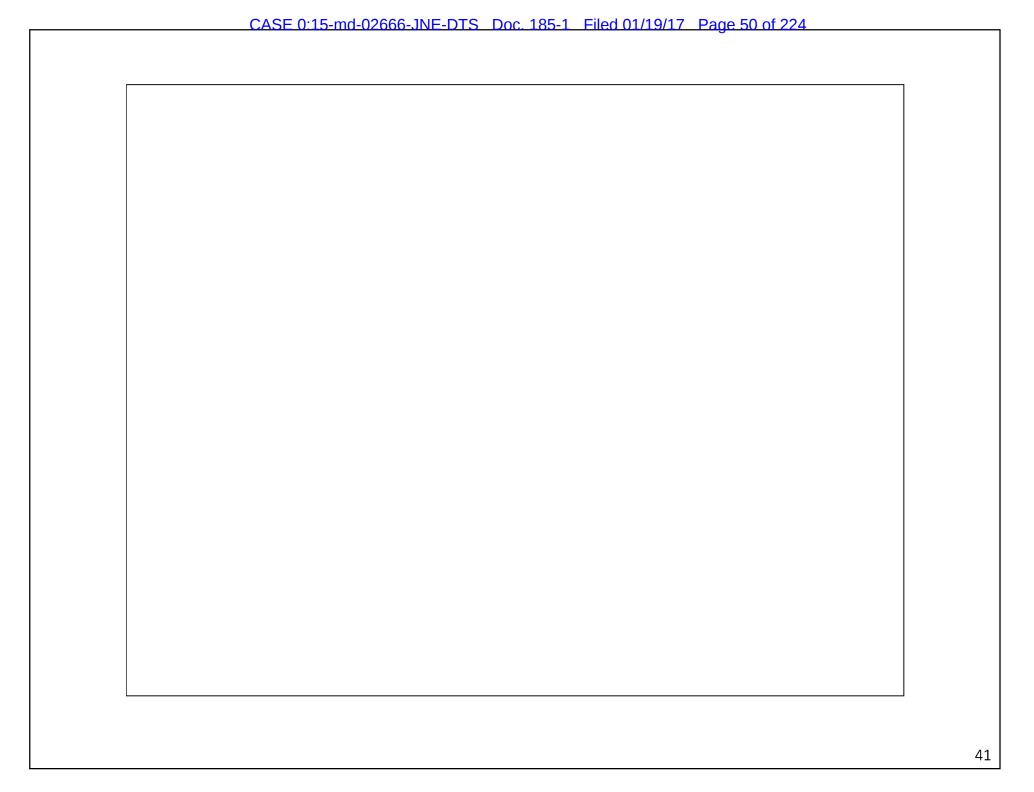
- Deep joint infection rates:
 - 9/' 08 6/' 10, Forced-air warming: 3.1% (1066 cases)
 - 7/' 10 1/' 11, HotDog warming : 0.81% (371 cases)
- Discontinuing the use of forced-air warming resulted in a 74% reduction in joint implant infections (p=0.024).
- Retrospective outcome study
- Contrast: ZERO outcome studies showing FAW safety

- A medium-sized independent regional healthcare network:
- Baseline PJI rate: FAW (t_{baseline} = 1 yr):
 - 1.55% 388 cases
- Study PJI rate: air-free conductive fabric warming/resistive electric warming (t_{study}=2 yr):
 - 0.29% 677 cases
- Decrease in PJI rate: 81%

(p = 0.027) 9/27/2016 5:22:08 PM



- An independent orthopedic and sports institute:
- Baseline PJI rate: FAW (t_{baseline} = 1 yr):
 - **2.29%**
 - 175 cases
- Study PJI rate: air-free conductive fabric warming/resistive electric warming (t_{study}=1 yr):
 - 0.00% 218 cases
- Decrease in PJI rate: 100% (p= 0.031)

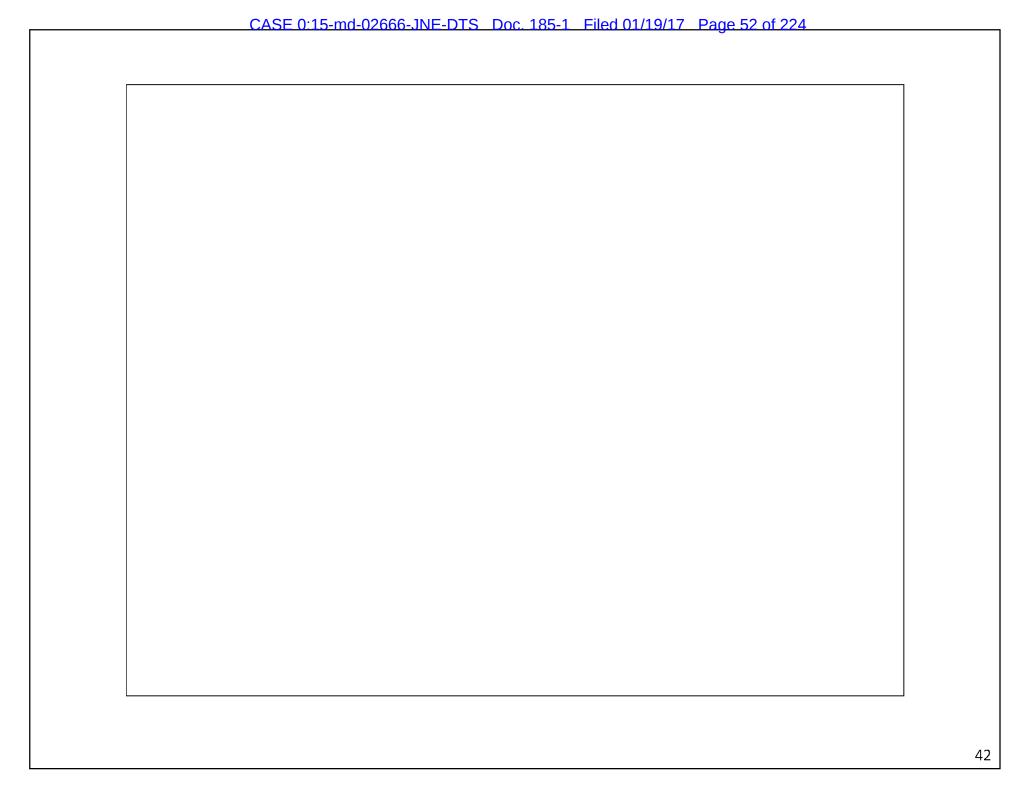


- A large general hospital:
- Baseline PJI rate: FAW (t_{baseline} = 1 yr):
 - **3.2%**

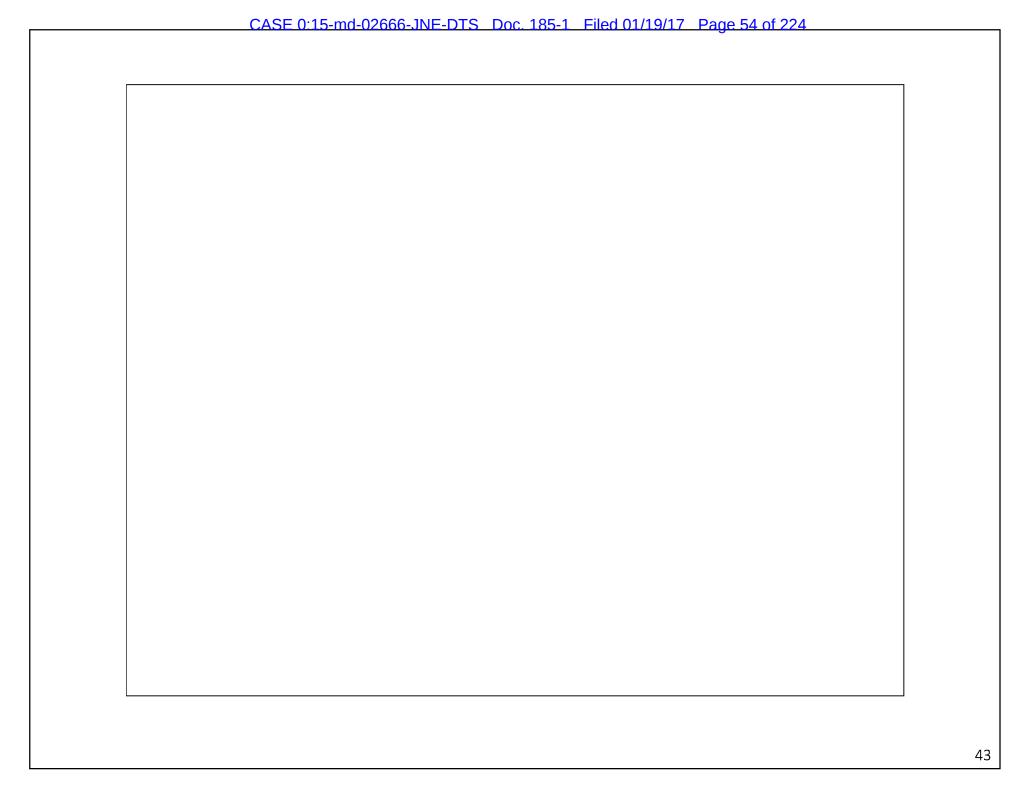
- 667 cases
- Study PJI rate: air-free conductive fabric warming/resistive electric warming (t_{study}=20 mo):
 - o.9%
- **1097 cases**

• Decrease in PJI rate: 72%

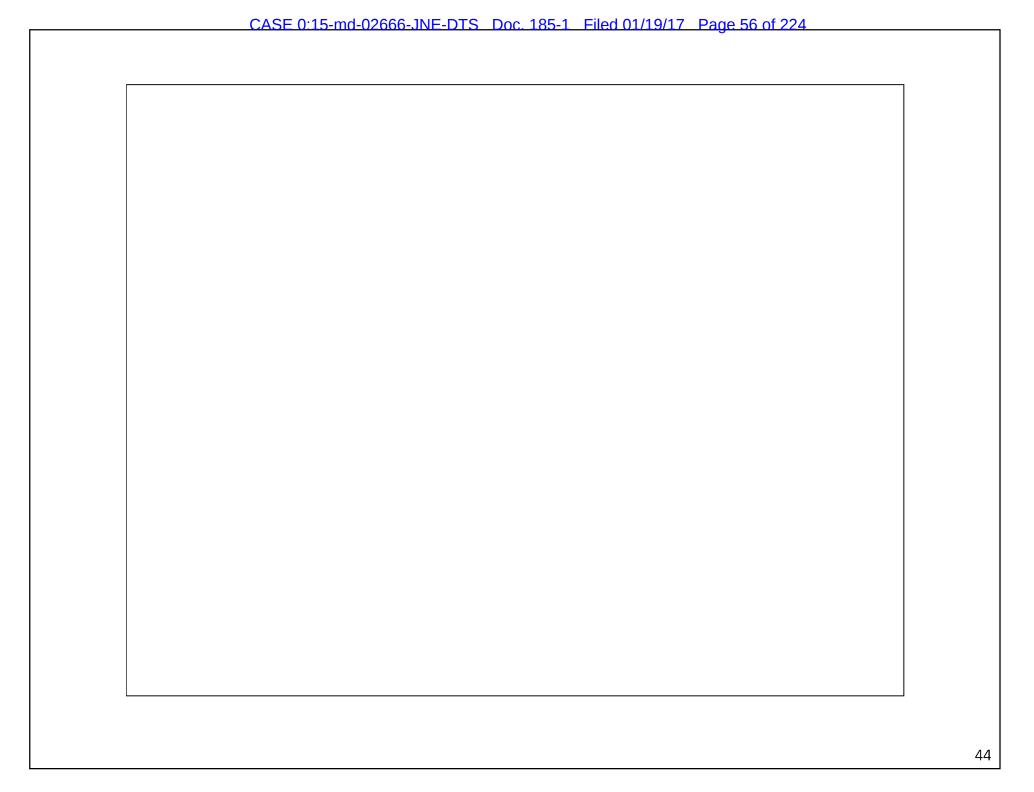
(p=0.00041)

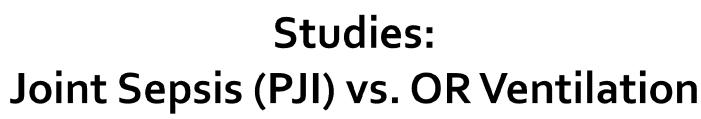


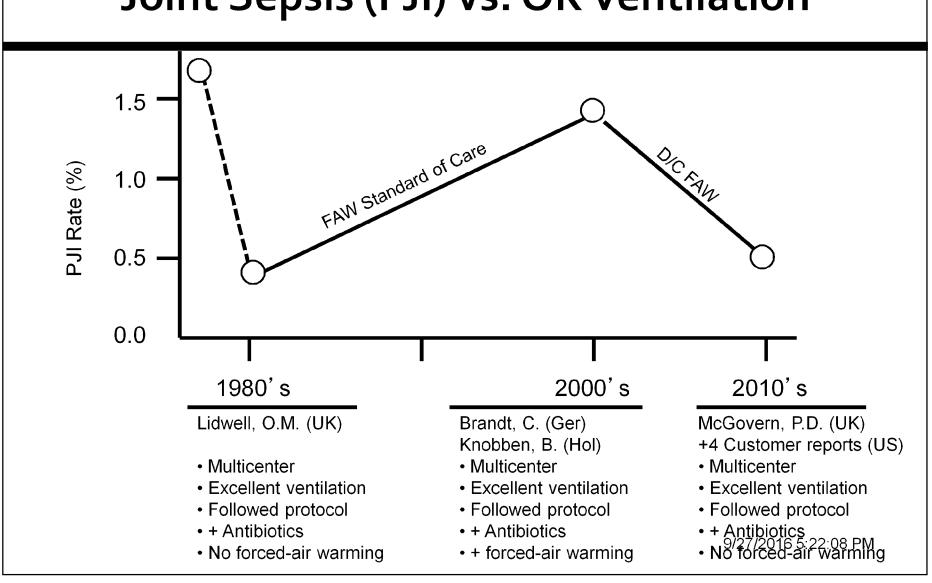
- A medium community hospital:
- Baseline PJI rate: FAW (t_{baseline} = 1 yr):
 - 1.57% 382 cases
- Study PJI rate: air-free conductive fabric warming/resistive electric warming (t_{study}= 6 mo):
 - 1.03% 194 cases
- Decrease in PJI rate: 34% (p = 0.045)



- Multicenter pooled results 4 hospitals:
- Baseline PJI rate: FAW (t_{baseline}):
 - 2.4% 1622 cases
- Study PJI rate: air-free conductive fabric warming/resistive electric warming (t_{study}):
 - 0.6% 2186 cases
- Decrease in PJI rate: 75% (p < 0.00001)

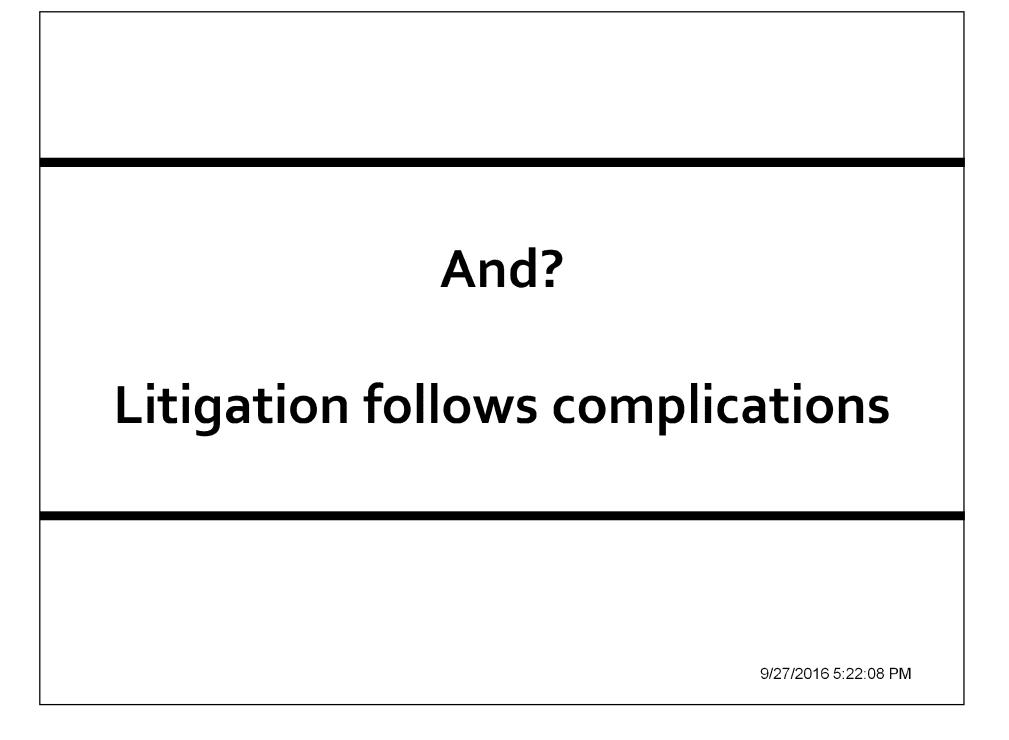






Today's lesson in summary

- The waste heat from FAW
 contaminates the sterile surgical field
 with bacteria, significantly increasing
 the risk of PJI.
- Therefore: PJI is the most common serious *anesthetic* complication.



Litigation

- Mass tort product liability action against a forcedair warming manufacturer started mid-August '15.
- Google search "Bair Hugger lawsuit" >> 100 law firms advertising for plaintiffs.
- TV advertising across the country.
- MDL certified in Mpls Federal Court. Dec. '15
- Expect more than 20,000 plaintiffs? (30,000 metalon-metal hips)

Why should clinicians care?

- Catastrophic injuries -> Permanent disability
- > 700 lawsuits so far against 3M
- With 20,000 PJIs per year (x6 years SOL); plenty of potential plaintiffs...and billions in potential damages.
- Product liability
 Medical Malpractice?
 - More deep pockets needed for tens of billions of dollars of liability.

"Learned intermediary" defense

- The 3M's response to the Court: the "learned intermediary" defense.
- Who/what is a "Learned Intermediary"?
 - It's you...and the surgeon and the anesthesiologist...and the hospital.
- 3M: The hospital and the providers knew the risks of using FAW and used it anyway so it's their fault, not the manufacturer.
- When 3M says FAW is "safe," don't believe it. They are already blaming you and they would love to have you share liability.

What should providers do?

- Switch to an air-free patient warming technology for all implant surgery. (Follow the CDC's recommendation)
- If the *hospital* refuses to switch (contracts for example):
 - Demand that the hospital indemnify you against liability in writing.
 - Add a discussion of the CDC warning and current FAW infection/contamination research to your standard informed consent.
- If you refuse to switch: remember, the "burden of proof" is on you to prove FAW safety. Informed consent is a must.

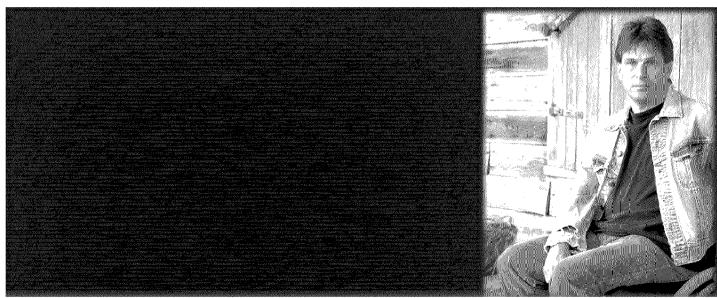
Take-away Message About Litigation

With 20,000 lawsuits predicted—plenty of opportunity for you to be involved....

Avoid if possible!

A closing thought to leave you with....

"Wave of New Litigation"



INFECTION FOLLOWING HIP OR KNEE REPLACEMENT SURGERY

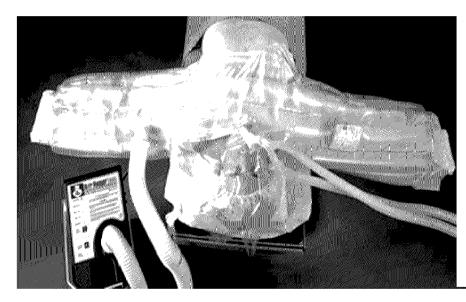


http://www.youtube.com/watch?v=-NBa6RdNuwl

Thank you!

saugustine@augbiomed.com

FAW vs. Conductive Fabric Warming





Bair Hugger® Warming

Augustine Medical Inc.
Arizant/3M

1000 watts, 40 CFM air

HotDog® Patient Warming

Augustine Temperature Management LLC.

200 watts, 0°CFM air

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EXHIBIT C

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From: David Bartel <dbartel99@gmail.com>

To: J Randall Benham <rbenham@augbiomed.com>

Sent: 2/3/2014 7:32:06 PM
Subject: Re: Research and analysis

Hi Randy,

We will not be back from Arizona until about the 20th of March. For selfish reasons, I want to celebrant my 65th birthday on March 15th in warm weather. My son and his wife live in Arizona so we have a great place to stay.

What you found includes the info from ThedaCare but as I said it was interesting to me that there was great concern about particles falling to the floor but no one talked about how it might be getting into the surgical site. After reading your research, I would have a lot of questions about how those particles got into the surgical site. I feel they talked around the subject but did not pin point the cause.

I think a video might be the answer too. Also I have done some webinars and conference talks. I would like to talk about 3M's influence on all the work I am doing. I can tell you I am not afraid of anyone and will do what I feel will stop MSRA. My loyalities are not one organization, if that organization is afraid of the truth. I will do anything to not have another person live through the pain I live with everyday. My story is not done. I am almost sure I am going to loose my hip. I am not sure I will be able to stay in Arizona as long as I want to because I am have lots of problems with my stump.

I spoke to David Hodges assistant who got some information from me to send to David. He is going to call me after he reviews the information.

Thank you for your response and let's keep talking. I hope we can have a face-to-face shortly after we get back unless you want to come to Arizona and get out of the cold too(haha).

Rosie

On Monday, February 3, 2014, J Randall Benham < rbenham@augbiomed.com> wrote: Rosie,

I searched as you suggested, and found this:

 $\frac{https://www.metastar.com/Web/portals/0/Documents/hospital}{/4\%20-\%20Health\%20Care\%20System\%20Journey\%20Improving\%20SSI.pdf}$

Is this what you had in mind, or is there more?

I also think you might be the person to help spread this message. If you have thoughts about how to do it, please let me know. One way might be a video in which you tell of your experience, describe the research you reviewed and provide your conclusion. It could go on our website and on the Internet.

This would, of course, irritate 3M. I'm not suggesting you would have any legal risk (you would not), but 3M could have influence even inside an organization like IHI. I don't want to sound too scary, but I also don't want you to be surprised.

So, when do you return from Arizona? Maybe I could drive over to Chilton for a face-to-face meeting.

Have you and David Hodges made contact? I think he is helping another lawyer file a case against Bair Hugger, so he may be swamped.

Randy

On 2/3/14 10:24 AM, "David Bartel" < dbartel99@gmail.com> wrote:

Hi Randy,

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The more I read your information the more I think this might be how I was infected. If you Google Rosie Bartel-MRSA, you will find a study I was involved in that ThedaCare looked at why they had surgical joint infects. It is interesting they spend a lot of time looking at the types of "germ particles" being brought into the OR and also how the patient is warmed but the do not come right out and say that the warming procedure is introducing infections into the surgical sites.

You wanted someone who is passionate about not using BarrHuggers, I might be your person. I am very concerned that the changes that "Think Rosie" campaign is making is not enough. You can make the changes that our study asked for and yet we will had many surgical joint infections.

You stated in your first e-mail to me that I do not want this to happen to someone else and you are right. I think we need to continue to talk. I believe your research is very compelling and I am excited to learn more about how I can help your cause.

Please keep in touch so we can spread the word of your research.

Rosie

On Thursday, January 30, 2014, J Randall Benham <rbenham@augbiomed.com 39;rbenham@augbiomed.com');> > wrote:

The Parvizi "white paper" was not included in the first email.

Randy

On 1/30/14 2:09 PM, "J Randall Benham" <rbenham@augbiomed.com> wrote:

Rosie,

I have assembled and attached quite a lot of the research, but there is now so much of it that I can't be sure I included everything. It falls into a few categories:

1. <u>Summaries and analyses</u>. The Chain of Infection document might be a good place to start; it provides a good overview. It was written by Dr. Augustine and an anesthesiologist colleague. The Summary of Published Research is also useful. This link maybe useful: http://www.hotdog-usa.com/research.php

If any of the cited research interests you, please let me know and I will attempt to provide a copy.

- 2. <u>Research re internal contamination.</u> The *Orthopedic Review* article, the article in *American Journal of Infection Control,* the Reed study and the Stanford poster address this issue. In summary, the articles suggest that forced-air blowers do not adequately filter the intake air, so the interior of the blowers become contaminated. The pathogens incubate inside the blowers and spew into the operating room.
- 3. <u>Research re convection currents</u>. The video that I sent previously shows this clearly. The McGovern study (also sent) confirms the video. The two Legg studies add further confirmation-- as does a study by Belani that I was unable to find this morning, but I did find a cite to the abstract: http://www.ncbi.nlm.nih.gov/pubmed/22822191

I have also included a "white paper" commissioned by 3M to explain why Bair Hugger is safe. This is not a peer-reviewed publication, but just a marketing piece paid for by 3M, but it gives you an idea of their position. In general, they obfuscate.

Finally, I have attached a Response to 3M that addresses the validity of their public defenses.

Rosie, I have communicated by email with David Hodges, the Texas attorney who filed the first case against Bair Hugger. When he responds, I will introduce the two of you by email—but then I need to remove myself from the conversation. Your conversations with David will only be privileged if no third parties are included.

Enjoy Arizona...

Randy

EXHIBIT D

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From: David Bartel <dbartel99@gmail.com>

To: J Randall Benham <rbenham@augbiomed.com>

Sent: 2/3/2014 4:24:26 PM Subject: Research and analysis

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Please keep in touch so we can spread the word of your research.

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On Thursday, January 30, 2014, J Randall Benham < rbenham@augbiomed.com > wrote:

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Randy

On 1/30/14 2:09 PM, "J Randall Benham" <rbenham@augbiomed.com> wrote:

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Enjoy Arizona...

Randy

EXHIBIT E

CASE 0:15-md-02666-JNE-DTS Doc. 185-1 Filed 01/19/17 Page 79 of 224

From: David Bartel <dbartel99@gmail.com>

To: J Randall Benham <rbenham@augbiomed.com>

Sent: 2/6/2014 2:08:48 AM
Subject: Re: Research and analysis

Randy,

We have more in common then you think. My husband is the convert of 40 years (there is story there too). He was a Catholic when I met him. I am an ex-nun and worked for the Catholic Church most of my life.

David and will be married 39 years in December. We have three children and four granddaughters but none on the way.

I think we will be great as we work together because our value systems are very much in line.

Rosie

On Wednesday, February 5, 2014, J Randall Benham < rbenham@augbiomed.com> wrote: Rosie,

We have a lot in common: Catholicism and focus on family may be the most important. I am a convert—15+ years ago after more than 20 years of weekly Mass with my cradle-Catholic wife. There is an oft-told story here that I will save for our meeting.

Patricia and I will celebrate 39 years in October. We have six kids and four grandsons (one more grandchild on the way). Our two youngest are still home. They are girls, 15 and 17, and both are adopted from China. The first four kids attended Catholic grade school, high school and college. We have home-schooled the girls, although Alexandria (the 17-year-old) is picking among three Catholic colleges in Minnesota.

Enough biography for now....I look forward to meeting you in person.

Randy

On 2/5/14 7:16 PM, "David Bartel" <dbartel99@gmail.com> wrote:

Hi Randy,

11:00 on the morning of the 19th will work great. There are lots of places for food. My daughter-in-law will make some suggestions for us and maybe my husband or she can pick it up while we talk or you can pick up before. We can talk more just before you come.

All the professional videos I have done in my past life were done for the Catholic Church and they own them. I was one of the key speakers and teacher for the Diocese of Green Bay. One of the losses I had due to MRSA was my job. It is one of the many things I miss most. I do not have much in personal videos because as my family says, I hate having my picture taken. I will see what I might have.

I look forward to working with you on the script. Filming at our home in Wisconsin will be great. That is where IHI did the filming of their video. I attended the 25th Annual Forum for IHI in December as a patient advisor. I can tell that my video, that you saw, has been seen across the country and internationally. At the Forum I was being stopped all the time by people saying: "Rosie, we saw your video and we loved the message." or "Rosie, we used your video with our staff and it changed how we are doing things."

As I have been talking to you, I have not said much about David, my husband, but he is very important to the work I am trying to do because as he says, "He is my VIP (very important pusher)". He will be with me on the 19th also. As you can probably tell, family is very important to me.

My son's address is: 868 E. Penny Lane, Queen Creek. My cell number is 920-517-7278.

Rosie

CASE 0:15-md-02666-JNE-DTS Doc. 185-1 Filed 01/19/17 Page 80 of 224 On Wednesday, February 5, 2014, J Randall Benham < repenham@augbiomed.com > wrote:

Rosie,

Mid-morning on the 19th preliminarily looks good to me. As I may have mentioned, I have family in Scottsdale, so I will spend the evening of the 18th with them and fly home late on the 19th. I expect a few hours will be enough to exhaust us both.

If there is good take-out nearby, maybe I could grab us some lunch and appear at your door around 11:00-11:30. Just let me know if some other time would be better.

In the meantime, I will create a very rough draft of a script—leaving lots of blank spaces for you to tell your story in your own words. I expect we will be swapping drafts until you are back in Wisconsin. We have video production capabilities in-house, so perhaps a couple of my colleagues and I could come to your home in Wisconsin for filming.

The story will be most powerful if it is personal. Do you have any video of your ordeal (or maybe life before your ordeal) that you would be willing to be made public?

Randy

On 2/5/14 1:45 PM, "David Bartel" < dbartel99@gmail.com'); > > wrote:

Hi Randy,

I am comfortable with your suggestions and I do believe, after reviewing the research, that forced-air warming in orthopedic implant surgery is a risk that should not be taken for safety reasons. I know you do not know me very well but I will tell you I would not be communicating with you if I did not find your research compelling.

I also feel that some face to face time is necessary for us to feel comfortable with each other. Either February 18 or 19 works for me. If you want to meet at my son's home we would need to work around his wife's schedule because she works from home. She said the afternoon of the 18th, the morning of the 19th, later on either afternoon or either evening. She works for a Wisconsin company so her workday is done about 4:00 pm.

Finally I am open to you writing a script. I have done lots of videos, webinars and conference talks and I have never used a script. I am an outline type of person. I do understand why you would like a script for this and I will be able to work with it. This being said, I think it will better for you to write the script and I do the edit and review.

Thank you for continuing this conversation. I did hear from David Hodges yesterday but he thinks the statue of limitations is run out on my claim unless he can find a loop hole.

Rosie

On Wednesday, February 5, 2014, J Randall Benham <rbenham@augbiomed.com 39;rbenham@augbiomed.com');> > wrote:

This is very logical, linear and concise. You obviously put a lot of thought into it.

I am comfortable with the outline. Your personal story and the general background are both critical. I do have a couple of requests for you to consider:

- 1. I hope you will mention Bair Hugger in the introduction. What you have learned about convection currents is the "news" of the video, and mentioning Bair Hugger early will foreshadow the ending nicely.
- 2. Although you are not a medical expert, you will be knowledgeable about the research and have every right to express your personal opinion. I hope your position is that using forced-air warming in orthopedic implant surgery is an unwise and unnecessary risk. If so, we ought to find a dramatic and memorable way to express this.

So, the next step would be to work on the actual script. Please tell me what role I should play. I am a writer at heart, so I could do a draft for your editing and review. I would be just as comfortable commenting on a first draft that you create. Your call.

If we have a working draft quickly enough, I would like to spend an afternoon with you in San Tan Valley—maybe February 18 or 19, if we can work quickly enough. To be blunt, I think we need to get to know each other a little. Our goals are

 $\hbox{CASE 0:} 15\text{-md-}02666\text{-JNE-DTS} \quad \hbox{Doc. 185-1} \quad \hbox{Filed 01/} 19/17 \quad \hbox{Page 81 of 224} \\ \hbox{similar, but not identical.} \quad \hbox{Obviously my colleagues and I care about patient safety, but we are also a business.} \quad \hbox{What we}$ are creating needs to meet both our our objectives. This requires a level of mutual trust that can't be achieved by email.

Randy

On 2/4/14 6:08 PM, "David Bartel" < dbartel99@gmail.com 39;dbartel99@gmail.com);> 39;dbartel99@gmail.com <u>39;39;dbartel99@gmail.com</u>');> ');> > wrote:

Outline thoughts:

- A. Introduction
- B. Personal story concerning my surgical infection
- C. My involvement in the Partnership for Patients study and what that study had learned:
 - a. Discussion about "foreign particles" being brought into operating rooms
 - b. Who and how those particles are brought into the room
 - 1. Patient and how they did use the surgical prep
 - 2. Nurses and doctors on clothing including the kind of undergarments
 - 3. Unnecessary equipment including personal laptops
 - c. How to decrease those particles
 - 1. Develop better instruction on how patients prepare for surgery at home
 - 2. Develop the "Think Rosie" campaign for hospital and clinic hand washing
 - 3. Instruct surgical personnel on what or what not to wear in surgery
 - 4. How to wear surgical attire
- D. What I have now learned about the Bair Huggers
 - a. Question why we did not ask:
 - 1. How the particles are getting to the surgical site from the floor
 - 2. Why the research about Bair Huggers was not talked about
 - b. My infection was from the knee replacement surgery
 - 1. I know I followed the prep to the letter
 - 2. My surgeon is very careful about who and what was brought into the room
 - 3. I am very healthy and I do not have diabetes, everyone asks due to amputation
 - 4. My surgery was more than two hours long so I probably had a Bair Huggers
- E. Closing thoughts

Randy,

You are welcome to meet us in Phoenix. My son lives in San Tan Valley or also known as Oueen Creek. An time would be good for us except February 12-14th. We are going to Las Vegas for a few day with our son and his wife.

I will begin working on an outline of my thought.

Rosie

On Monday, February 3, 2014, J Randall Benham <rbenham@augbiomed.com> wrote:

Rosie,

I have family in Scottsdale and a SW Airlines ticket that has to be used before it expires, so a meeting in Phoenix is not out of the question. (I'd rather not let this languish for almost two months.)

In the meantime, however, let's think more about the video. Perhaps you could sketch a very rudimentary outline. I can then make comments and suggestions...and the process can continue.

Before law school, I was a journalist, so I pride myself on being able to write a bit. It would feel a little wrong, however, for me to write a first draft. This is your story, and the words ought to be yours. I am a better editor than writer, however, so maybe I can assist in that manner.

By the way, my 65th will be July 2— so we may have some history in common.

Randy

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On 2/3/14 1:32 PM, "David Bartel" < dbartel99@gmail.com> wrote:

Hi Randy,

We will not be back from Arizona until about the 20th of March. For selfish reasons, I want to celebrant my 65th birthday on March 15th in warm weather. My son and his wife live in Arizona so we have a great place to stay.

What you found includes the info from ThedaCare but as I said it was interesting to me that there was great concern about particles falling to the floor but no one talked about how it might be getting into the surgical site. After reading your research, I would have a lot of questions about how those particles got into the surgical site. I feel they talked around the subject but did not pin point the cause.

I think a video might be the answer too. Also I have done some webinars and conference talks. I would like to talk about 3M's influence on all the work I am doing. I can tell you I am not afraid of anyone and will do what I feel will stop MSRA. My loyalities are not one organization, if that organization is afraid of the truth. I will do anything to not have another person live through the pain I live with everyday. My story is not done. I am almost sure I am going to loose my hip. I am not sure I will be able to stay in Arizona as long as I want to because I am have lots of problems with my stump.

I spoke to David Hodges assistant who got some information from me to send to David. He is going to call me after he reviews the information.

Thank you for your response and let's keep talking. I hope we can have a face-to-face shortly after we get back unless you want to come to Arizona and get out of the cold too(haha).

Rosie

On Monday, February 3, 2014, J Randall Benham <<u>rbenham@augbiomed.com</u>> wrote: Rosie,

I searched as you suggested, and found this:

https://www.metastar.com/Web/portals/0/Documents/hospital/4%20-%20Health%20Care%20System%20Journey%20Improving%20SSI.pdf

Is this what you had in mind, or is there more?

I also think you might be the person to help spread this message. If you have thoughts about how to do it, please let me know. One way might be a video in which you tell of your experience, describe the research you reviewed and provide your conclusion. It could go on our website and on the Internet.

This would, of course, irritate 3M. I'm not suggesting you would have any legal risk (you would not), but 3M could have influence even inside an organization like IHI. I don't want to sound too scary, but I also don't want you to be surprised.

So, when do you return from Arizona? Maybe I could drive over to Chilton for a face-to-face meeting.

Have you and David Hodges made contact? I think he is helping another lawyer file a case against Bair Hugger, so he may be swamped.

Randy

On 2/3/14 10:24 AM, "David Bartel" <

EXHIBIT F

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From: David Bartel <dbartel99@gmail.com>

J Randall Benham <rbenham@auqbiomed.com> To:

Sent: 5/21/2014 9:09:43 PM

Re: Website-- legal resources Subject:

Hi Randy,

This is done very well. I found the different law firms' website information interesting. I think the concern for the issue is growing. I wish I knew 3-5 years ago what I know today. As we struggle financially under the weight of a growing amount of medical bills. I do wonder if I am doing the smart thing. It is sad that I probably waited to long to do anything.

I am sorry I am a little sad today but it seems like everyday has a new problem lately.

Thank you for being our friend. I usually do not tell anyone about the pain or the tough stuff. I really trust Brent and you.

Rosie

On Wednesday, May 21, 2014, J Randall Benham <rbenham@augbiomed.com> wrote: Rosie,

It was nice to talk with you yesterday. Your energy always invigorates me.

You mentioned an interest in adding legal resources to the web site. As I said, we have identified several lawyers around the country who seem to be aware of the risks of forced-air warming in orthopedic surgery.

If you approve, we could add the following to the site in the Resources section:

Feel Like Suing?

Although I have decided not to sue (so far, at least), others have. I know of two cases that have been filed against 3M, the company that makes Bair Hugger forced-air warmers, the device that almost all hospitals use. One case is in Texas (http://www.prweb.com/releases/2013/3/prweb10554160.htm) and the other is in Kansas (http://www.prweb.com/releases /2014/03/prweb11708249.htm). Neither one sued their doctor, but only the manufacturer of the forced-air warming device.

The lawyer that filed these cases even runs an ad looking for others who have been injured. (Bair Hugger Infections Web

If you have talked to a lawyer, you probably came away disappointed. I certainly was. Most believe that proving the cause of an infection is just too difficult. They have not read the research published in the last few years.

Google searching uncovered the names of a few other plaintiffs' lawyers looking for these cases. I listed them below. I expect there are others.

Kansas

Sexton Law

http://www.mikesextonlaw.com/

Minnesota

Lord & Faris

http://www.faris-faris.com/bair-hugger/

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Pritkzer

http://www.pritzkerlaw.com/medical-malpractice/periprosthetic-joint-infection.html

New York, New Jersey, Florida, Washington D.C.

Parker Waichman LLP

http://www.yourlawyer.com/blog/texas-man-claims-bair-hugger-surgery-blanket-infected-hip-implant/

New York

Rheingold, Valet, Rheingold, McCartney & Giuffra

http://www.rheingoldlaw.com/blog/2013/06/is-the-bair-hugger-device-a-danger-for-patients.shtml

<u>Texas</u>

KennedyHodges

http://www.kennedyhodges.com/

Hale Law

http://www.lawfirmnewswire.com/2013/08/attorney-with-the-hale-law-firm-comments-on-personal-injury-lawsuit-filed-in-houston/

Pennsylvania

Caroselli Beachler McTiernan & Conboy

http://www.cbmclaw.com/Defective-Products/Bair-Hugger-Forced-Air-Warming-Device.shtml

EXHIBIT G

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From: To: Rosie Bartel kenham@augbiomed.com

Sent:

7/28/2015 9:20:48 PM

Subject:

Re: Update

That sounds good to me. Keep in touch.

Rosie

On Tuesday, July 28, 2015, Randy Benham < rbenham@augbiomed.com > wrote:

Let s skip him, then. If you agree, I will talk to Priscilla Lord, here in town. I have known her for 20 years, and she is a pretty well-known personal injury attorney.

Here is her website:

http://www.mnlordlaw.com/serious-infection-amputation-surgical-implant-bair-hugger-warmer-device/

From: Rosie Bartel < bartel1949@gmail.com > Date: Tuesday, July 28, 2015 at 3:05 PM

To: Randy Benham <rbenham@augbiomed.com>

Subject: Re: Update

Randy,

Remember, we did contact him through you back when we first met. He was check on Wisconsin law and he never got back to us. If you have some way of connecting with him and checking about his feels on Wisconsin laws, go for it. I gave up on him having interest in my case after not hearing from him.

Let me know what you think.

Rosie

On Tuesday, July 28, 2015, Randy Benham < rbenham@augbiomed.com > wrote:
I am so sorry about your granddaughter. Every Sunday, on my knees after Communion, I say a quick thanks and then, & keep them safe, keep them safe, keep them safe. Loving people can be very painful .

I saw that some of the websites had incorporated your site. I have no clue about the rules and legalities, but it seems that common courtesy would demand that they drop you a note.

Rosie, I would suggest you talk to David Hodges at the Kennedy Hodges firm in Houston. He is the first lawyer who became interested in the research. He filed the first cases, and he knows more about this than anyone. As much as anyone in his line of work can be trusted, I think he can. (I know that sounds harsh, but your tragedy is his business.)

If you like, I will make an introduction.

Randy

From: Rosie Bartel <bartel1949@gmail.com>
Date: Tuesday, July 28, 2015 at 2:46 PM

To: Randy Benham <rbenham@augbiomed.com>

Subject: Re: Update

Hi Randy,

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First, I have been ok physically but David and my heart are breaking over our 18 year old granddaughter. She was diagnosed with stage three lymphoma in early June. She starts her third round of chemo tomorrow. She is very sick and we are struggling with the why.

Second, I am having a little change of heart about suing. It is hard to do presentations to hospitals and physicians when they act like it can never be their fault. Also, I am surprised that several of the Bear Hugger lawyers are using my story in the information yet none of them have ever contacted me.

My question to you is: Who would you recommend to talk to and why?

Talk to you soon.

Rosie

On Tuesday, July 28, 2015, Randy Benham <rbenham@augbiomed.com> wrote: Rosie,

I thought I would let you know what is going on regarding forced-air warming. Things have sort of exploded in the last week or so. Five lawsuits were filed against Bair Hugger on Friday, with plaintiffs from four different states. Suddenly personal injury lawyers are all over the Internet, looking for victims of Bair Hugger. Just search &Bair Hugger lawyer on Google you li get 50+ hits, and many of them are telling the story quite knowledgeably.

Last I heard, you and David had decided not to sue (well, David may not have been so sure). Given the stress and distraction of litigation, that may still be the right choice. If you have reconsidered, however, there a lots of lawyers who would like to talk to you.

Enough of that . How are you? I fear you will tell me there has been another surgery, but please keep me informed my prayers require specifics.

Hi to David.

Randy

EXHIBIT H

Privilege Log

Identification:

- S. Augustine, CEO Augustine Temperature Management
- B. Augustine, President, Augustine Temperature Management

Sue Augustine, principal, Augustine Biomedical + Design

Elaina Reinke, former employee of Augustine Temperature Management

Warren Loken, employee, Augustine Biomedical + Design

- R. Benham, General Counsel Augustine Temperature Management
- D. Hodges, attorney
- G. Assaad, attorney
- J. Neuman, attorney
- B. Gordon, attorney
- G. Zimmerman, attorney
- S. Davis, attorney
- A. Go, Kennedy Hodges law clerk
- D. Grewe, executive employee of Augustine Temperature Management

	Document Type	Date and time of Document	Author(s)	Recipient(s)	Persons Copied/Forward ed	Subject Matter/Specific Litigation	Basis for Claim of Privilege
1	Email	10-19-15 10:35 am	Hodges	Benham		Walton Doc 98 Order Regarding Rulings from 10-13- 15 Telephone Conference	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
2	Email	8-19-15 12:08 pm	Benham	Hodges		Walton (possibly Johnson and others)/FDA 1997	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
3	Email	8-19-15 2:15 pm	Benham	Hiodges		Walton (possibly Johnson and others)/Hepa	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
4	Email	11-5-15 11:55 am	Hodges	Benham		Walton and Johnson/Noel Order	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product

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							related to same
5	Email stream	8-11-15 10:58 am	Hodges	Benham	Grewe, S. Augustine, B. Augustine	Walton (possibly Johnson and others)/ 3M Video on BH safety	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
6	Email	7-23-15 2:40 pm	Hodges	Benham	Assaad	Walton and Johnson/Depos	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
7	Email	8-19-15 5:22 pm	Benham	Hodges		Walton (possibly Johnson and others)/ Hepa	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
8	Email	9-21-15 3:36 pm	Hodges	Benham		Walton (possibly Johnson and others)//Privilege	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
9	Email	9-21-15 2:42 pm	Benham	Hodges		Walton (possibly Johnson and others)//Privilege	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
10	Email stream	5-20-14 12:10 pm 5-20-14 2:35 pm 5-20-14 3;23 PM	Benham Go Benham	Hodges Benham Go (as Temp User 3)		Walton (possibly Johnson and others)//Research for review by potential experts	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
		5-28-14 4:05 pm	Go	Benham			
11	Email	5-20-14	Hodges	Benham	Assaad	Walton (possibly	Hodges Work Product

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	stream	2:25 pm 5-19-14 10:17 am 5-20-14 2:29 pm	Hodges Benham	Benham Hodges	Assaad	Johnson and others)//Literature review for potential experts	related to Augustine Role as Non-testifying expert; Benham work product related to same
		5-20-14	Hodges	Benham	Assaad		
12	Email	9-14-15 4:40 pm	Hodges	Benham		Walton (possibly Johnson and MDL)/ 3M response to JPML motion	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
13	Email	10-13-15 3:10 pm	Hodges	Benham, Gordon, Zimmerman		Walton (possibly Johnson and MDL)/ Scheduling	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
14	Email	1-19-15 2:26 pm	Assaad	Benham	Hodges, Green, Neuman	Walton (possibly Johnson and MDL)/ BH marketshare	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
15	Email	6-15-15	Assaad	Benham		Walton (possibly Johnson and MDL)/ literature	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
16	Email	2-8-15	Assaad	Benham	Hodges	Walton (possibly Johnson and MDL)/ depositions	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
17	Email	6-26-13 11:16 am	Hodges	Benham	Assaad	Walton (possibly Johnson and MDL)/ communications	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same

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18	Email	9-12-13 1:55 pm	Hodges	Benham	Assaad	Johnson litigation	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
19	Email	8-26-15 8:19 am	Green	Benham		Walton litigation/discovery	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
20	Email	9-23-15 4:34 pm	Hodges	Benham		Walton and Johnson/deposition scheduling	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
21	Email	5-5-14 2:37 pm	Hodges	Benham	Assaad	Walton (possibly Johnson and MDL)/ Expert issues	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
22	Email stream	11-6-13 1:36 pm 11-5-13 6:08 pm	Hodges Hodges	Benham Benham	Assaad	Johnson Resending Johnson/ file review	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
23	Email	9-18-25 2:34 pm	Hodges	Benham		Johnson/ Transmittal of Texas court documents	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
24	Email stream	9-18-15 12:09 pm 9-16-15 11:01 am	Green Benham	Benham		Walton and Johnson/ Minnesota discovery issues	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same

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		9-15-15 5:37 pm	Benham (includes undated initiating email from Green)	Green			
25	Email	11-14-13 9:06 am	Hodges	Benham	Assaad, Neuman	Walton/ Amended Complaint re misrepresentations	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
26	Email	11-5-13 5:39 pm	Hodges	Benham	Assaad	Walton/ fraud allegations	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
27	Email	7-29-13 1:00 pm	Hodges	Benham	Assaad	Walton/transmittal of court documents	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
28	Email	9-16-15 6:18 pm	Hodges	Benham	Assaad, Green	Walton/ Motion to Compel	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
29	Email	11-3-151 12:29 pm	Benham	Hodges		Walton (possibly Johnson and MDL)/ Communications/ FAW manufacturers	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
30	Email	9-18-15 9:12 am	Hodges	Benham		Walton and Johnson/Motion to Compell	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
31	Email	5-14-14 1:45 pm	Hodges	Benham	Assaad	Johnson/Expert issues	Hodges Work Product related to Augustine Role

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							as Non-testifying expert; Benham work product related to same
32	Email	6-27-13 1:45 pm	Hodges	Benham	Assaad	Walton (possibly Johnson and MDL)/ General information re litigation against 3M	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship. Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
33	Email	6-7-13 12:00 pm	Hodges	Benham	Assaad	Walton (possibly Johnson and MDL)/ Communications re litigation against 3M	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship. Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
34	Email	5-21-13 5:42 pm	Hodges	Benham	Assaad, S. Augustine	Walton (possibly Johnson and MDL)/ Communications re litigation against 3M	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine

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							relationship. Attorney- client privilege based on Benham-Augustine relationship.
35	Email	12-1-14 10:46 am	Neumann	Benham	Hodges, Assaad	Johnson/ expert witness issues	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same.
36	Email	9-24-5 11:55 AM	Green	Benham	Hodges, Assaad	Walton and Johnson/ Discovery issues	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship.
37	Email stream	7-18-13 5:02 PM	Hodges	Grewe	Assaad, Benham	Potential New Jersey litigation	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship.
		7-18-13 3;56 PM	Grewe	Hodges	Assaad		rotation.p.
		7-18-13 4:03 pm	Hodges	Hodges	Grewe, Assaad		
		7-18-13 1:58 pm	Hodges	Hodges	Grewe, Assaad		
		7-18-13 10:58 am	Hodges	Hodges	Grewe		

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	1		1		1			
			7-17-13 8:55 pm 7-3-13 3:13 pm	Davis Hodges	Hodges Davis			
			7-1-13 10:17 pm	Davis	Hodges			
			7-1-13 2:30 pm	Hodges	Davis			
38		Email	8-1-13 1:29 pm	Benham	Hodges	Grewe, Assaad, S. Augustine	Legal research regarding potential liability of 3M for infections caused by Bair Hugger	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney- client privilege based on Hodges-Augustine relationship. Attorney- client privilege based on Benham-Augustine relationship.
39		Email	10-11-13 12:13 pm	Benham	Hodges	Assaad	3M information	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship.
40		Email	10-30-15 3:55 pm	Hodges	Benham, Gordon	Zimmerman	Scheduling communications	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same.
41		Email	7-23-13	Assaad	Benham	Grewe	Query re	Hodges Work Product

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	stream	3:33 pm 7-23-13 1:42 pm	Benham	Assaad	Grewe	communications	related to Augustine Role as Non-testifying expert; Benham work product related to same.
42	Email stream	9-2-15 8:43 am 9-1-15 8:21 pm	Green Benham	Benham	Assaad Assaad	Walton/Case status	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same.
		9-1-15 7:25 pm	Benham	Green	Assaad		
		8-26-15 8:19 am	Green	Benham	Assaad		
43	Email stream	9-1-15 6:46 pm	Green	Benham	Assaad	Walton/ discovery issues	Hodges Work Product related to Augustine Role
		8-31-15 11:57 am	Benham	Green	Assaad		as Non-testifying expert; Benham work product related to same.
		8-26-15 8:19 am	Green	Benham	Assaad		
44	Email stream	6-12-14 11:25 am	Hodges	Benham		Walton (possibly Johnson and MDL)/ published research	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same.
		11:12 am	Benham	Hodges			
45	Email	3-29-13 10:29 am	Hodges	Lindsay Stevic (unknown)	Benham	Walton (possibly Johnson and MDL	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
46	Email stream	6-9-14 4:15 pm	Hodges Benham	Benham Hodges		Bair Hugger litigation generally	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same

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		6-9-14 2:36 pm					
47	Email	12-18-15	Hodges	Benham		Walton and Jiohnson/ deposition scheduling	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
48	Email stream	9-16-13 2:07 pm 9-16-13 11:20 am	Hodges Benham	Benham Hodges	Assaad	Potential Bair Hugger litigation/ analysis of statue of limitation	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Benham work product individually.
49	Email stream	5-5-14 4:09	Hodges	Benham	Assaad	Walton (possibly Johnson and MDL	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
50	Email stream	6-6-13 11:02 am 6-6-13 9:55 am	Hodges Benham	Benham Hodges	Assaad, B. Augustune, S. Augustine	Walton, Potential Bair Hugger litigation, scheduling issues, research, communications re	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
		5-28-13 9:02 am	Hodges	Benham	Assaad, S. Augustine	litigation	
		5-28-13 2:55 pm	Benham	Hodges	Assaad, S. Augustine		
		5-28-13 10:35 a	Benham	Hodges			
51	Email stream	10-21-15 12:08 pm	Hodges Benham	Benham, Assaad Hodges,		Walton (possibly Johnson and MDL/published research	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same
		10-21-13	Dellialli	i louges,			TOIGLEG TO SAITE

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		11:54 am		Assaad			
52	Email stream	8-5-13 3:31 PM 8-5-13 3;20 pm	Hodges Benham	Benham, Faris Hodges, Faris	Assaad	Potential Bair Hugger litgation/analysis of legal issues	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Benham work product individually.
53	Email	3-29-13	Hodges	Benham		Walton/ communications re litigation	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same.
54	Email stream	6-28-13 11:04 am	Hodges	Grewe, Benham	Assaad	Potential Bair Hugger litgation/analysis of legal and fact issues,	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-
		6-28-13 10:48 am	Grewe	Hodges, Benham	Assaad	communications	client privilege based on Hodges-Augustine relationship. Attorney-
		6-28-13 10:48 am	Hodges	Grewe, Benham	Assaad		client privilege based on Benham-Augustine relationship; Benham work
		6-28-13 9:40 am	Grewe	Hodges, Benham	Assaad		product individually
		6-27-13 4:37 pm	Hodges	Grewe, Benham	Assaad		
		6-27-13 4;21 PM	Grewe	Hodges, Benham	Assaad		
		6-27-13 4;23 PM	Hodges	Grewe, Benham	Assaad		
		6-27-13 4:01 pm	Grewe	Hodges, Benham	Assaad		
		6-27-13 3:33 pm	Benham	Hodges	Grewe, Assaad		

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55	Email stream	6-7-13 1:18 pm 6-7-13 1:18 pm 6-7-13	Hodges Benham Hodges	Benham, Assaad Hodges, Assaad Benham	S. Augustine, B. Augustine S. Augustine, B. Augustine	Walton, potential Bair Hugger litgation/analysis of legal and fact issues, communications	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine
		12:51 pm 6-7-13 12:49 pm 6-7-13 11:23 pm	Benham Benham	Hodges, Assaad Hodges, Assaad	S. Augustine, B. Augustine S. Augustine, B. Augustine		relationship; Benham work product individually
56	Email stream	5-22-13 2:35 pm 5-22-13 12:04 pm	Hodges Benham	Benham	Assaad, S. Augustine Assaad, S. Augustine	Walton, potential Bair Hugger litgation/analysis of legal and fact issues, communications	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship; Benham work product individually
57	Email stream	12-3-14 2;16 pm	Hodges	Benham, Neuman	Assaad	Walton, (possibly Johnson and MDL)/ recent research, expert issues	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-

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		12-3-14 2:05 pm 12-2-14 3:19 pm 12-1-14 10:46 am	Benham Benham Neuman	Hodges, Neuman Neuman Benham	Assaad Hodges, Assaad		client privilege based on Hodges-Augustine relationship. Attorney- client privilege based on Benham-Augustine relationship; Benham work product individually
58	Email stream	9-23-13 4:43 pm 9-23-13 3:40 PM	Hodges Benham	Benham, Assaad Hodges, Assaad	S. Augustine, B. Augustine, S. Augustine, B. Augustine	Legal analysis re potential Bair Hugger litigation	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship; Benham work product individually
59	Email stream	7-2-13 12:44 pm 7-2-13 12:03 pm	Hodges Benham	Benham, Grewe, Hodges, Grewe	Assaad	Walton, (possibly Johnson and MDL)/ recent research	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship; Benham work product individually
60	Email stream	11-5-15 12:29-pm 11-5-15 12:27 pm 11-5-15 12:20 pm	Hodges Benham Hodges	Benham Hodges Benham		Walton and Joihnson/ discovery issues	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same

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		11-5-15	Benham	Hodges			
		12:18 pm	201110111				
		11-5-15 11:54 pm	Hodges	Benham			
61	Email	7-3-13	Hodges	Benham		Walton, potential	Hodges Work Product
	stream	6:36 pm	riouges	Bermani		Bair Hugger litgation/analysis of legal and fact issues, communication issues	related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney- client privilege based on
		7-3-13 1:59 pm	Benham	Hodges		100000	Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine
		7-3-13 1;37 pm	Hodges	Benham			relationship; Benham work product individually
		7-3-13 11:58 am	Benham	Hodges			
62	Email stream	2-3-14 5:17 pm	Hodges	Benham, Assaad		Analysis of potential Bair Hugger litigation, pathogen analysis, communication issues	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-
		2-3-14 3:55 pm	Benham	Hodges, Assaad			
		2-3-14 3:49 pm	Hodges	Benham, Assaad			client privilege based on Benham-Augustine relationship; Benham work
		2-3-14 3:10 pm	Benham	Hodges, Assaad			product individually
		1-30-14 11:45 am	Benham	Hodges, Assaad			
63	Email stream	11-14-13 3:24 pm	Hodges	Benham	Assaad, Neuman	Walton(possibly Johnson and MDL)/ analysis of legal issues re misrepresentation	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-

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		11-14-13 12:33 pm	Benham	Hodges	Assaad, Neuman		client privilege based on Hodges-Augustine relationship. Attorney- client privilege based on Benham-Augustine relationship; Benham work product individually
64	Email stream	2-19-14 7:38 pm	Hodges	Benham	Assaad	Potential Bair Hugger litigation, Johnson, communications issues	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-
		2-19-14 7:32 pm	Benham	Hodges	Assaad		client privilege based on Hodges-Augustine relationship. Attorney-
		2-19-14 3:07 pm	Hodges	Benham	Assaad		client privilege based on Benham-Augustine relationship; Benham work product individually
		2-17-14 12:17 pm	Benham	Hodges	Assaad		
		2-17-14 12:06 pm	Hodges	Benham	Assaad		
		2-17-14 10:09 am	Benham	Hodges	Assaad		
65	Email stream	9-16-15 11:00 am	Green	Benham		Walton, Johnson discovery issues	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product
		9-15-15 5:37 pm	Benham	Green			related to same. Attorney- client privilege based on Hodges-Augustine
		9-15-15 5:11 pm	Green	Benham			relationship. Attorney-client privilege based on Benham-Augustine relationship
66	Email stream	2-5-14 2:33 pm	Hodges	Benham	Assaad	Potential Bair Hugger litigation, analysis of legal	Hodges Work Product related to Augustine Role as Non-testifying expert;
		2-5-14 12:28 pm	Benham	Hodges	Assaad	issue related to potential plaintiff,	Benham work product related to same. Attorney-

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		2-5-14 10:29 am 2-5-14 10:06 am 2-4-14 6:03 pm	Hodges Benham Hodges	Benham Hodges Benham	Assaad Assaad Assaad	communications issues	client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship; Benham work product individually
67	Ema		Hodges Benham	Benham, Assaad Hodges, Assaad	S. Augustine S. Augustine	Potential Bair Hugger litigation, analysis of legal issue related to potential plaintiff	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship; Benham work product individually
68	Ema		Hodges Benham	Benham Hodges	Grewe	Walton(possibly Johnson and other potential plaintiffs)/response s to queries re elements of proof	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship; Benham work product individually
69	Ema		Hodges Benham Hodges	Benham Hodges Benham	Assaad Assaad	Johnson/ issues regarding specific pathogens, Augustine analysis, scheduling	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney- client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on

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		12-16-13 11:53 am	Benham	Hodges	Assaad		Benham-Augustine relationship
70	Email stream	5-14-14 4:15 pm 5-14-14 2:40 pm	Hodges Benham	Benham, Assaad Hodges, Assaad	S. Augustine S. Augustine	Johnson/ Analysis of issues re infection prevention protocols and specific pathogens	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship
71	Email stream	11-20-13 5:55 pm 11-18-13 3:56 PM	Hodges Benham	Benham Hodges	Assaad, Neuman, S. Augustine Assaad, Neuman, S. Augustine	Walton(possibly Johnson and other potential plaintiffs)/ Analysis of competitive and scientific literature	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship
72	Email stream	9-12-14 10:45 am 9-12-14 10:44 am 9-12-14 10:14 am	Hodges Benham Hodges	Benham Hodges Benham	Assaad Assaad Assaad	Walton/ Analysis of scientific literature and use in discovery	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship
73	Email stream	7-3-13 7:50 pm 7-3-13 12:12 pm	Hodges Benham	Benham Hodges	Grewe	Potential Bair Hugger litigation/ analysis of scientific, legal and market issues	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-

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							client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship
74	Email stream	7-11-13 12:36 pm 7-10-13 2:00 pm	Hodges Benham	Benham Hodges	Assaad, Grewe, S. Augustine Assaad, Grewe, S. Augustine	Potential Bair Hugger litigation/ analysis of scientific, legal and market issues, communications re potential litigation	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney- client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship
75	Email	4-20-15 11:08 am	Hodges	Benham	Assaad	Walton, Johnson/ discovery issue	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship
76	Email stream	5-12-14 12:53 pm 5-7-14 2:30 pm	Hodges Benham	Benham, Neuman, Assaad Hodges, Neuman, Assaad		Walton/ Analysis of factual background of market and research	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship; Benham work product individually
77	Email	9-14-14	Neuman	Benham,	Assaad	Walton,	Hodges Work Product

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	stream	9-9-14 3:35 pm 9-9-14 3:28 pm 9-9-14 2:08 pm 8-27-14 6:02 pm	Benham Hodges Benham Neuman	Hodges, Neuman Benham Neuman Benham	Assaad Hodges, Assaad Hodges, Assaad	Johnson/Discussio n regarding discovery and deponents	related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship
78	Email stream	4-8-13 2:18 pm 4-8-13 1:32 pm 4-5-13 5:44 pm 4-5-13 3:35 pm	Hodges Benham Hodges Benham	Benham, Augustine Hodges Benham Hodges		Potential Bair Hugger litigation/ Discussion re interest in litigation	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney- client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship
79	Email stream	6-27-13 12:22 pm 6-27-13 12:19 pm 6-27-13 11:55 am	Hodges Benham Hodges	Benham Hodges Benham	Grewe, S.Augustine Grewe, S. Augustine	Potential Bair Hugger litigation/ analysis of elements of proof, discussion re interest in litigation	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney- client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship

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			6-26-13 9:04 am	Benham	Hodges	Grewe, S. Augustine		
80			2-3-15 10:34 am	Assaad	Benham	Hodges	Walton, Johnson (possibly other MDL cases)/ discussion re	Hodges Work Product related to Augustine Role as Non-testifying expert;
			1-26-15 12:22 pm	Benham	Assaad		market data, infection data analysis, discovery	Benham work product related to same. Attorney- client privilege based on Hodges-Augustine
			1-26-15 12:08 pm	Assaad	Benham		issues	relationship. Attorney-client privilege based on
			1-26-15 12:02 pm	Benham	Assaad	Hodges, S. Augustine		Benham-Augustine relationship
			1-26-15 10:48 am	Assaad	Benham			
81	En		2-11-15 10:24 am	Assaad	Benham		Walton, Johnson (possibly other MDL cases)/ discussion re published research	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship
82	Em	mail 8	8-25-15	Green	Benham	Hodges, Assaad	Walton, Johnson/ discussion re discovery issues	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship

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83	Email	4-23-15	Neuman	Benham	Walton, Johnson (possibly other MDL cases)/ discussion re potential litigation, evidence, communications	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship
84	Email	1-26-15 10:48 am	Assaad	Benham	Walton, Johnson (possibly other MDL cases)/ discussion re forced-air warming market, discovery issues	Hodges Work Product related to Augustine Role as Non-testifying expert; Benham work product related to same. Attorney-client privilege based on Hodges-Augustine relationship. Attorney-client privilege based on Benham-Augustine relationship
85	Email	7-22-15 12:06 pm	Benham	B. Augustine, Grewe, S. Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham- Augustine relationship
86	Email	8-11-16 11:13 am	Benham	Grewe, S. Augustine, B. Augustine, Sue Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham- Augustine relationship
87	Email	1-18-16 2:44 pm	Benham	Grewe, S. Augustine, B. Augustine, Sue Augustine, G. Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham- Augustine relationship
88	Email	8-8-16 1:31 pm	Benham	Grewe, S. Augustine, B.	Legally appropriate communications re	Attorney-client privilege based on Benham-

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				Augustine, Sue Augustine	Bair Hugger litigation and research	Augustine relationship
89	Email	7-6-16 3: 40 PM	Benham	Grewe, S. Augustine, B. Augustine, Sue Augustine, G. Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham- Augustine relationship
90	Email	10-15-15 2:15 PM	Benham	Grewe, S. Augustine, B. Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham-Augustine relationship
91	Email	3-22-16 12:20 pm	Benham	Grewe, S. Augustine, B. Augustine, E. Reinke	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham- Augustine relationship
92	Email	8-4-16 2:34 pm	Benham	Grewe, S. Augustine, B. Augustine, Sue Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham-Augustine relationship
93	Email	1-22-15 10:01 am	Benham	Grewe, B. Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham-Augustine relationship
94	Email	11-16-16 10:35 am	Benham	Grewe, S. Augustine, B. Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham- Augustine relationship
95	Email	7-29-15 11:17 am	Benham	Grewe, S. Augustine, B. Augustine, G. Augustine,	Legally appropriate communications re Bair Hugger litigation and	Attorney-client privilege based on Benham- Augustine relationship

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				Reinke	research	
96	Email	1-21-15 2:29 pm	Benham	Grewe, S. Augustine, B. Augustine, Sue Augustine, G. Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham-Augustine relationship
97	Email	12-17-15 12:01 pm	Benham	Grewe, S. Augustine, B. Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham-Augustine relationship
98	Email	7-7-16 10:20 am	Benham	Grewe, S. Augustine, B. Augustine, Sue Augustine, G. Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham-Augustine relationship
99	Email	12-8-15 2:55 pm	Benham	Grewe, S. Augustine, B. Augustine, Loken, G. Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham-Augustine relationship
100	Email	12-8-15 12:18 pm	Benham	Grewe, S. Augustine, B. Augustine, Loken, G. Augustine, Reinke	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham-Augustine relationship
101	Email	5-10-16 3:27 pm	Benham	Grewe, S. Augustine, B. Augustine, G. Augustine, Sue Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham-Augustine relationship
102	Email	1-12-16 11:54 am	Benham	Grewe, B. Augustine, , Sue	Legally appropriate communications re Bair Hugger	Attorney-client privilege based on Benham-Augustine relationship

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				Augustine	litigation and research	
103	Email	9-19-16 3:39 pm	Benham	Grewe, S. Augustine, B. Augustine, G. Augustine, Sue Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham-Augustine relationship
104	Email	12-15-15 12:45 pm	Benham	Grewe, S. Augustine, B. Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham-Augustine relationship
105	Email	12-15-15 2:11 pm	Benham	Grewe, S. Augustine, B. Augustine, G. Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham-Augustine relationship
106	Email	9-19-16 3:09 pm	Benham	Grewe, S. Augustine, B. Augustine, G. Augustine, Sue Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham-Augustine relationship
107	Email	8-24-16 11:54 am	Benham	Grewe, S. Augustine, B. Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham-Augustine relationship
108	Email	8-8-16 1:31 pm	Benham	Grewe, S. Augustine, B. Augustine, Sue Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham- Augustine relationship
109	Email	2-1-14 3:06 pm	Benham	Grewe, S. Augustine, B. Augustine	Legally appropriate communications re Bair Hugger litigation and	Attorney-client privilege based on Benham-Augustine relationship

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					research	
110	Email	8-4-16 2:34 pm	Benham	Grewe, S. Augustine, B. Augustine, Sue Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham- Augustine relationship
111	Email	6-24-15 11:35 am	Benham	Grewe, S. Augustine, B. Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham- Augustine relationship
112	Email	9-1-16 11:51 am	Benham	Grewe, S. Augustine, B. Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham-Augustine relationship
113	Email	7-3-15 12:21 pm	Benham	Grewe	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham- Augustine relationship
114	Email	1-18-16 1:29	Benham	Grewe, Sue Augustine	Legally appropriate communications re Bair Hugger litigation and research	Attorney-client privilege based on Benham- Augustine relationship

EXHIBIT I

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IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS HOUSTON DIVISION

Plaintiff,

V.

S

CIVIL ACTION NO. H-13-1164

S

3M COMPANY, ARIZANT HEALTHCARE, S
INC., and ROBERT PRESTERA,

Defendants.

<u>ORDER</u>

Before the Magistrate Judge upon referral from the District Judge is Defendant 3M Company's Motion to Compel Plaintiff's Responses to Discovery (Document No. 103). In that motion, Defendant seeks an Order compelling Plaintiff to provide a response to Defendant's "Supplemental Interrogatory No. 1", and produce documents responsive to Request for Production No. 1, both of which seek information about Plaintiff's contacts and communications with Dr. Scott Augustine. In response to the motion, Plaintiff and his counsel represent that they have had no contact or communications with Dr. Augustine relative to this case, other than a telephone call between Plaintiff's counsel and Dr. Augustine about meetings Dr. Augustine had with Mr. Maharaj in 2008 and 2009. As for any other communications and contacts, Plaintiff's counsel has advised that his law firm, Kennedy Hodges, LLC, represented Dr. Augustine's company, Augustine Biomedical + Design, LLC, in 2009, and maintains that any communications and contacts related to that representation are privileged.

Having considered Defendant's Motion to Compel, Plaintiff's response in opposition, the disclosure of the contacts Plaintiff and his counsel have had with Dr. Augustine related to this case,

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and the fact that Dr. Augustine is not a consulting or testifying expert for Plaintiff in this case, it is

ORDERED that Defendant's Motion to Compel (Document No. 103) is DENIED.

Defendant may, of course, seek discovery directly from Dr. Augustine, who has been identified by Plaintiff as a fact witness, through a deposition and/or a subpoena.

Signed at Houston, Texas, this /d/ day of May, 2015.

UNITED STATES MAGISTRATE JUDGE

auest. Story

EXHIBIT J

Privilege Log

Identification:

- S. Augustine, CEO Augustine Temperature Management
- B. Augustine, President, Augustine Temperature Management
- R. Benham, General Counsel Augustine Temperature Management
- D. Hodges, attorney
- G. Assaad, attorney
- J. Neuman, attorney
- D. Grewe, executive employee of Augustine Temperature Management

	Document Type	Date of Document	Author(s)	Recipient(s)	Persons Copied	Subject Matter	Category of Privilege
1	Email series	2/1/13	S. Augustine, D. Hodges	D. Hodges, S. Augustine	R. Benham	Litigation: consulting relationship and potential product liability, unfair competition and/or other claims.	Attorney/Client: Benham/Augustine; Hodges/Benham- Augustine. Work product: all attorneys.
2	Email series	4/8/13	R. Benham, D. Hodges	R. Benham, D. Hodges	S. Augustine	Litigation: sharing information regarding scheduling of communications and other information re potential product liability, unfair competition and/or other claims.	Attorney/Client: Benham/Augustine; Hodges/Benham- Augustine. Work product: all attorneys
3	Email series	4/29/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation: sharing information regarding scheduling of communications and facts re potential product liability, unfair	Attorney/Client: Benham/Augustine; Hodges-Assaad/Benham- Augustine. Work product: all attorneys

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						competition and/or other claims.	
4	Email series	4/30/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation: sharing information regarding scheduling of communications and facts re potential product liability, unfair competition and/or other claims.	Attorney/Client: Benham/Augustine; Hodges-Assaad/Benham- Augustine. Work product: all attorneys
5	Email series	5/1/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation: sharing information regarding scheduling of communications and facts re potential product liability, unfair competition and/or other claims.	Attorney/Client: Benham/Augustine; Hodges-Assaad/Benham- Augustine. Work product: all attorneys
6	Email series	5/15/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation: sharing information regarding potential product liability, unfair competition and/or other claims.	Attorney/Client: Benham/Augustine; Hodges-Assaad/Benham- Augustine. Work product: all attorneys
7	Email series	5/21/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation: sharing information regarding potential product liability, unfair competition and/or other claims	Attorney/Client: Benham/Augustine; Hodges-Assaad/Benham-Augustine. Work product: all attorneys
8	Email series	5/22/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation: sharing information regarding potential product liability, unfair competition and/or other claims	Attorney/Client: Benham/Augustine; Hodges-Assaad/Benham- Augustine. Work product: all attorneys

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9	Email series	5/28/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation: sharing information regarding potential product liability, unfair competition and/or other claims	Attorney/Client: Benham/Augustine; Hodges-Assaad/Benham- Augustine. Work product: all attorneys
10	Email series	5/29/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation: sharing information regarding scheduling of communications and facts re potential product liability, unfair competition and/or other claims.	Attorney/Client: Benham/Augustine; Hodges-Assaad/Benham- Augustine. Work product: all attorneys
11	Email series	5/31/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation: sharing information regarding scheduling of communications and facts re potential product liability, unfair competition and/or other claims.	Attorney/Client: Benham/Augustine; Hodges-Assaad/Benham-Augustine. Work product: all attorneys
12	Email series	6/6/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine, B. Augustine	Litigation: sharing information regarding scheduling of communications and facts re potential product liability, unfair competition and/or other claims.	Attorney/Client: Benham/S.Augustine-B. Augustine; Hodges- Assaad/Benham-S. Augustine-B. Augustine Work product: all attorneys
13	Email series	6/7/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine, B. Augustine	Litigation: sharing information regarding potential product liability, unfair competition	Attorney/Client: Benham/S.Augustine-B. Augustine; Hodges- Assaad/Benham-S. Augustine-B. Augustine

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						and/or other claims	Work product: all attorneys
14	Email series	6/27/13	R. Benham, D. Hodges	R. Benham, D. Hodges	S. Augustine, D. Grewe	Litigation: sharing information regarding potential product liability, unfair competition and/or other claims	Attorney/Client: Benham/Augustine; Hodges-Assaad/Benham- Augustine. Work product: all attorneys
15	Email series	7/18/13	R. Benham, D. Hodges	R. Benham, D. Hodges	S. Augustine, D. Grewe, G. Assaad	Litigation: sharing information regarding potential product liability, unfair competition and/or other claims	Attorney/Client: Benham/S.Augustine-D. Grewe; Hodges- Assaad/Benham-S. Augustine-D. Grewe Work product: all attorneys
16	Email series	8/1/13	R. Benham, D. Hodges	R. Benham, D. Hodges	S. Augustine, D. Grewe, G. Assaad	Litigation: sharing information regarding potential product liability, unfair competition and/or other claims	Attorney/Client: Benham/S.Augustine-D. Grewe; Hodges- Assaad/Benham-S. Augustine-D. Grewe Work product: all attorneys
17	Email series	9/23/13	R. Benham, D. Hodges, G. Assaad	R. Benham, D. Hodges, G. Assaad	S. Augustine, B. Augustine	Litigation: sharing information regarding potential product liability, unfair competition and/or other claims	Attorney/Client: Benham/S.Augustine-B. Augustine; Hodges- Assaad/Benham-S. Augustine-B. Augustine Work product: all attorneys
18	Email series	11/20/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, J. Neuman, S. Augustine	Litigation: sharing information regarding potential product liability, unfair competition and/or other claims	Attorney/Client: Benham/S.Augustine; Hodges-Assaad- Neuman/Benham-S. Augustine Work product: all attorneys
19	Email series	12/3/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, J. Neuman, S. Augustine	Litigation: sharing information regarding potential	Attorney/Client: Benham/S.Augustine; Hodges-Assaad-

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						product liability, unfair competition and/or other claims	Neuman/Benham-S. Augustine Work product: all attorneys
20	Email series	2/6/14	R. Benham, D. Hodges, G. Assaad	R. Benham, D. Hodges, G. Assaad	S. Augustine	Litigation: sharing information regarding potential product liability, unfair competition and/or other claims	Attorney/Client: Benham/S.Augustine; Hodges-Assaad-/Benham- S. Augustine Work product: all attorneys
21	Email series	5/14/14	R. Benham, D. Hodges, G. Assaad	R. Benham, D. Hodges, G. Assaad	S. Augustine	Litigation: sharing information regarding potential product liability, unfair competition and/or other claims	Attorney/Client: Benham/S.Augustine; Hodges-Assaad-/Benham- S. Augustine Work product: all attorneys
22	Email series	1/26/15	G. Assaad, R. Benham, D. Hodges	G. Assaad, R. Benham, D. Hodges	S. Augustine	Litigation: sharing information regarding potential product liability, unfair competition and/or other claims	Attorney/Client: Benham/S.Augustine; Hodges-Assaad-/Benham- S. Augustine Work product: all attorneys
23	Email series	2/9/15	G. Assaad, R. Benham	G. Assaad, R. Benham	D. Hodges, S. Augustine	Litigation: sharing information regarding scheduling of communications and facts re potential product liability, unfair competition and/or other claims.	Attorney/Client: Benham/S.Augustine; Hodges-Assaad-/Benham- S. Augustine Work product: all attorneys

EXHIBIT K

Dr. Jerry Myers CEO and Chief Medical Director Kell West Regional Hospital 5420 Kell West Boulevard Wichita Falls, TX 76310-1610

August 10, 2016

Re: Liability Avoidance at Kell West Regional Hospital

Dear Dr. Myers,

Thank you for the trial of HotDog® patient warming at Kell West Regional Hospital. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

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Cost savings

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Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

- 1. The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
- 2. Current research suggests that 75% of these are easily avoidable by discontinuing FAW.
- 3. PJIs costs \$100,000-150,000 each and are not reimbursed by Medicare and many insurers.
- 4. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the very wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

PS: We're hearing that many hospitals have been told there are <u>no</u> issues with forced-air warming in total joint surgery. If this is true for you, ask the manufacturer for indemnification.

- 1. McGovern et al. Forced-air warming and ultra-clean ventilation do not mix. J Bone and Joint Surg-Br. 2011;93(11):1537-1544.
- Centers for Disease Control and Prevention (CDC.gov) available at: https://www.cdc.gov/hicpac/pdf/mm/November%205-6%202015HICPAC-Meeting Summary Final-508.pdf
- 3. Dasari et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. Anaesthesia 2012;67:244-249.
- 4. Legg et al. Do forced air patient-warming devices disrupt unidirectional downward airflow? J Bone and Joint Surg-Br. 2012;94-B:254-6.
- 5. Belani et al. Patient warming excess heat: The effects on orthopedic operating room ventilation performance. Anesthesia & Analgesia 2013 Aug;117(2):406-11
- Legg, AJ and Hamer AJ. Forced-air patient warming blankets disrupt unidirectional airflow. Bone and Joint Journal, March 2013 vol. 95-B no. 3 407-410
- 7. Scherrer M. Hygiene and room climate in the operating room. Min Invas Ther & Allied Tech 2003;12(6);293-299.
- 8. Moretti B et al. Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infections? J Hosp Infect 2009;73:58-63
- 9. Albrecht M, Leaper D et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. Am J Infect Control 2011;39:321-8.
- Reed M et al. Forced Air Warming Design: An Evaluation of Intake Filtration, Internal Microbial Build-Up, and Airborne-Contamination Emissions. AANA Journal 2013;81(4):275-280
- 11. Mahoney CB, Odom J. Maintaining intraoperative normothermia: a meta-analysis of outcomes with costs. AANA Journal 1999; 67: 155-163
- 12. Sun Z, Honar H, Sessler DI, et al. Intraoperative core temperature patterns, transfusion requirement, and hospital duration in patients warmed with forced air. Anesthesiology 2015;122:276-85
- 13. Hayashi, H; Koizumi, T; Sumita, S.; Yamakage, M. Relative clinical heat transfer effectiveness: Forced-air warming vs. Conductive fabric electric warming. ASA abstract 2015. Submitted for publication.

Ms. Fran Lindemann CFO Kell West Regional Hospital 5420 Kell West Boulevard Wichita Falls, TX 76310-1610

Cc: Dr. Jerry Myers, CEO and Chief Medical Director

August 10, 2016

Re: Liability Avoidance at Kell West Regional Hospital

Dear Ms. Lindemann,

Thank you for the trial of HotDog® patient warming at Kell West Regional Hospital. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

In general terms, the use of forced-air warming is antithetical during implant surgery. "Nothing that blows air should be in an operating theater, if possible," according to experts from the Centers for Disease Control and Prevention (CDC) and advisors from the Healthcare Infection Control Practices Advisory Committee. "[I]t is important," the warning continues, "not to blow air in the operating theater."

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Some of the suits have named the hospital and surgeon as co-defendants, although most of the suits merely cite the hospital and surgeon. You should know that 3M has been using the "learned intermediary defense" in these suits. In short, 3M argues that they had no duty to warn the patient or the public, because they provided the doctors and hospital (the "learned intermediary") with all of the warnings that were required. In my opinion, this is an attempt to shift the blame from them to you and your staff. Switching to an air-free warming technology is the best protection for your orthopedic surgery patients—and for Kell West Regional Hospital.

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Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

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Again I compliment you on the very wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

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- 14. McGovern et al. Forced-air warming and ultra-clean ventilation do not mix. J Bone and Joint Surg-Br. 2011;93(11):1537-1544.
- 15. Centers for Disease Control and Prevention (CDC.gov) available at: https://www.cdc.gov/hicpac/pdf/mm/November%205-6%202015HICPAC-Meeting_Summary_Final-508.pdf
- 16. Dasari et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. Anaesthesia 2012;67:244-249.
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- 20. Scherrer M. Hygiene and room climate in the operating room. Min Invas Ther & Allied Tech 2003;12(6);293-299.
- 21. Moretti B et al. Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infections? J Hosp Infect 2009;73:58-63
- 22. Albrecht M, Leaper D et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. Am J Infect Control 2011;39:321-8.
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- 24. Mahoney CB, Odom J. Maintaining intraoperative normothermia: a meta-analysis of outcomes with costs. AANA Journal 1999; 67: 155-163
- 25. Sun Z, Honar H, Sessler DI, et al. Intraoperative core temperature patterns, transfusion requirement, and hospital duration in patients warmed with forced air. Anesthesiology 2015;122:276-85
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General Counsel Kell West Regional Hospital 5420 Kell West Boulevard Wichita Falls, TX 76310-1610

Cc: Dr. Jerry Myers, CEO and Chief Medical Director

August 10, 2016

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Dear General Counsel,

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- 28. Centers for Disease Control and Prevention (CDC.gov) available at: https://www.cdc.gov/hicpac/pdf/mm/November%205-6%202015HICPAC-Meeting_Summary_Final-508.pdf
- 29. Dasari et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. Anaesthesia 2012;67:244-249.
- 30. Legg et al. Do forced air patient-warming devices disrupt unidirectional downward airflow? J Bone and Joint Surg-Br. 2012;94-B:254-6.
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- 32. Legg, AJ and Hamer AJ. Forced-air patient warming blankets disrupt unidirectional airflow. Bone and Joint Journal, March 2013 vol. 95-B no. 3 407-410
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Mr. Bill O'Brien Risk Manager Kell West Regional Hospital 5420 Kell West Boulevard Wichita Falls, TX 76310-1610

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August 10, 2016

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- 44. Belani et al. Patient warming excess heat: The effects on orthopedic operating room ventilation performance. Anesthesia & Analgesia 2013 Aug;117(2):406-11
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- 52. Hayashi, H; Koizumi, T; Sumita, S.; Yamakage, M. Relative clinical heat transfer effectiveness: Forced-air warming vs. Conductive fabric electric warming. ASA abstract 2015. Submitted for publication.

Chief of Anesthesia Kell West Regional Hospital 5420 Kell West Boulevard Wichita Falls, TX 76310-1610

Cc: Dr. Jerry Myers, CEO and Chief Medical Director

August 10, 2016

Re: Liability Avoidance at Kell West Regional Hospital

Dear Chief of Anesthesia,

Thank you for the trial of HotDog® patient warming at Kell West Regional Hospital. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

In general terms, the use of forced-air warming is antithetical during implant surgery. "Nothing that blows air should be in an operating theater, if possible," according to experts from the Centers for Disease Control and Prevention (CDC) and advisors from the Healthcare Infection Control Practices Advisory Committee. "[I]t is important," the warning continues, "not to blow air in the operating theater."

Liability Avoidance

There are now nine (9) published studies showing that the waste heat from FAW contaminates the sterile surgical field. You may know that 3M is facing nearly 500 lawsuits alleging that their Bair Hugger® FAW is causing catastrophic periprosthetic joint infections ("PJI"). These suits have been consolidated into one Federal Court and have been certified as a Multi-District Litigation. It is expected that there could be over 20,000 suits filed before this matter is resolved.

Some of the suits have named the hospital and surgeon as co-defendants, although most of the suits merely cite the hospital and surgeon. You should know that 3M has been using the "learned intermediary defense" in these suits. In short, 3M argues that they had no duty to warn the patient or the public, because they provided the doctors and hospital (the "learned intermediary") with all of the warnings that were required. In my opinion, this is an attempt to shift the blame from them to you and your staff. Switching to an air-free warming technology is the best protection for your orthopedic surgery patients—and for Kell West Regional Hospital.

HotDog® Patient Warming is More Effective

Warming patients during surgery is not simply an exercise to satisfy Medicare SCIP requirements. Warm surgical patients have better outcomes and fewer complications—one study showed the cost of a hypothermic patient is between \$2,500-\$7,000. You may be aware that Bair Hugger FAW has been shown in a large study to fail over 30% of the time. A failure rate that high has significant hidden costs.

HotDog is the only practical warming technology that is *more* effective than FAW. HotDog simultaneously warms from both above and below the patient, resulting in much higher warming rates.¹³

Cost savings

The switch to HotDog warming will save between 20% and 70% off of your current FAW costs.

Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

- 17. The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
- 18. Current research suggests that 75% of these are easily avoidable by discontinuing FAW.
- 19. PJIs costs \$100,000-150,000 each and are not reimbursed by Medicare and many insurers.
- 20. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the very wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

PS: We're hearing that many hospitals have been told there are <u>no</u> issues with forced-air warming in total joint surgery. If this is true for you, ask the manufacturer for indemnification.

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Ms. Cindi Lane Infection Control Kell West Regional Hospital 5420 Kell West Boulevard Wichita Falls, TX 76310-1610

Cc: Dr. Jerry Myers, CEO and Chief Medical Director

August 10, 2016

Re: Liability Avoidance at Kell West Regional Hospital

Dear Ms. Lane,

Thank you for the trial of HotDog® patient warming at Kell West Regional Hospital. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

In general terms, the use of forced-air warming is antithetical during implant surgery. "Nothing that blows air should be in an operating theater, if possible," according to experts from the Centers for Disease Control and Prevention (CDC) and advisors from the Healthcare Infection Control Practices Advisory Committee. "[I]t is important," the warning continues, "not to blow air in the operating theater."

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Some of the suits have named the hospital and surgeon as co-defendants, although most of the suits merely cite the hospital and surgeon. You should know that 3M has been using the "learned intermediary defense" in these suits. In short, 3M argues that they had no duty to warn the patient or the public, because they provided the doctors and hospital (the "learned intermediary") with all of the warnings that were required. In my opinion, this is an attempt to shift the blame from them to you and your staff. Switching to an air-free warming technology is the best protection for your orthopedic surgery patients—and for Kell West Regional Hospital.

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Cost savings

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Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

- 21. The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
- 22. Current research suggests that 75% of these are easily avoidable by discontinuing FAW.
- 23. PJIs costs \$100,000-150,000 each and are not reimbursed by Medicare and many insurers.
- 24. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

PS: We're hearing that many hospitals have been told there are <u>no</u> issues with forced-air warming in total joint surgery. If this is true for you, ask the manufacturer for indemnification.

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- 78. Hayashi, H; Koizumi, T; Sumita, S.; Yamakage, M. Relative clinical heat transfer effectiveness: Forced-air warming vs. Conductive fabric electric warming. ASA abstract 2015. Submitted for publication.

Chief of Orthopedics Kell West Regional Hospital 5420 Kell West Boulevard Wichita Falls, TX 76310-1610

Cc: Dr. Jerry Myers, CEO and Chief Medical Director

August 10, 2016

Re: Liability Avoidance at Kell West Regional Hospital

Dear Chief of Orthopedics,

Thank you for the trial of HotDog® patient warming at Kell West Regional Hospital. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

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Liability Avoidance

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Some of the suits have named the hospital and surgeon as co-defendants, although most of the suits merely cite the hospital and surgeon. You should know that 3M has been using the "learned intermediary defense" in these suits. In short, 3M argues that they had no duty to warn the patient or the public, because they provided the doctors and hospital (the "learned intermediary") with all of the warnings that were required. In my opinion, this is an attempt to shift the blame from them to you and your staff. Switching to an air-free warming technology is the best protection for your orthopedic surgery patients—and for Kell West Regional Hospital.

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HotDog is the only practical warming technology that is *more* effective than FAW. HotDog simultaneously warms from both above and below the patient, resulting in much higher warming rates.¹³

Cost savings

The switch to HotDog warming will save between 20% and 70% off of your current FAW costs.

Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

- 25. The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
- 26. Current research suggests that 75% of these are easily avoidable by discontinuing FAW.
- 27. PJIs costs \$100,000-150,000 each and are not reimbursed by Medicare and many insurers.
- 28. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

PS: We're hearing that many hospitals have been told there are <u>no</u> issues with forced-air warming in total joint surgery. If this is true for you, ask the manufacturer for indemnification.

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- 91. Hayashi, H; Koizumi, T; Sumita, S.; Yamakage, M. Relative clinical heat transfer effectiveness: Forced-air warming vs. Conductive fabric electric warming. ASA abstract 2015. Submitted for publication.

OR Manager Kell West Regional Hospital 5420 Kell West Boulevard Wichita Falls, TX 76310-1610

Cc: Dr. Jerry Myers, CEO and Chief Medical Director

August 10, 2016

Re: Liability Avoidance at Kell West Regional Hospital

Dear OR Manager,

Thank you for the trial of HotDog® patient warming at Kell West Regional Hospital. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

In general terms, the use of forced-air warming is antithetical during implant surgery. "Nothing that blows air should be in an operating theater, if possible," according to experts from the Centers for Disease Control and Prevention (CDC) and advisors from the Healthcare Infection Control Practices Advisory Committee. "[I]t is important," the warning continues, "not to blow air in the operating theater."

Liability Avoidance

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Cost savings

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Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

- 29. The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
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- 32. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

PS: We're hearing that many hospitals have been told there are <u>no</u> issues with forced-air warming in total joint surgery. If this is true for you, ask the manufacturer for indemnification.

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Ms. JoAnn Nolan Purchasing Kell West Regional Hospital 5420 Kell West Boulevard Wichita Falls, TX 76310-1610

Cc: Dr. Jerry Myers, CEO and Chief Medical Director

August 10, 2016

Re: Liability Avoidance at Kell West Regional Hospital

Dear Ms. Nolan,

Thank you for the trial of HotDog® patient warming at Kell West Regional Hospital. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

In general terms, the use of forced-air warming is antithetical during implant surgery. "Nothing that blows air should be in an operating theater, if possible," according to experts from the Centers for Disease Control and Prevention (CDC) and advisors from the Healthcare Infection Control Practices Advisory Committee. "[I]t is important," the warning continues, "not to blow air in the operating theater."

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Warm regards,

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Mr. Kevin Vaziri President Woodland Healthcare 1325 Cottonwood Street Woodland, CA 95695-5199

August 10, 2016

Re: Liability Avoidance at Woodland Healthcare

Dear Mr. Vaziri,

Thank you for the trial of HotDog® patient warming at Woodland Healthcare. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.

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HotDog is the only practical warming technology that is *more* effective than FAW. HotDog simultaneously warms from both above and below the patient, resulting in much higher warming rates.¹³

Cost savings

The switch to HotDog warming will save between 20% and 70% off of your current FAW costs.

Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

- 37. The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
- 38. Current research suggests that 75% of these are easily avoidable by discontinuing FAW.
- 39. PJIs costs \$100,000-150,000 each and are not reimbursed by Medicare and many insurers.
- 40. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the very wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

PS: We're hearing that many hospitals have been told there are <u>no</u> issues with forced-air warming in total joint surgery. If this is true for you, ask the manufacturer for indemnification.

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Chief Financial Officer Woodland Healthcare 1325 Cottonwood Street Woodland, CA 95695-5199

Cc: Mr. Kevin Vaziri, President

August 10, 2016

Re: Liability Avoidance at Woodland Healthcare

Dear Chief Financial Officer,

Thank you for the trial of HotDog® patient warming at Woodland Healthcare. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.

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General Counsel Woodland Healthcare 1325 Cottonwood Street Woodland, CA 95695-5199

Cc: Mr. Kevin Vaziri, President

August 10, 2016

Re: Liability Avoidance at Woodland Healthcare

Dear General Counsel,

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Ms Theresa Childers Risk Manager Woodland Healthcare 1325 Cottonwood Street Woodland, CA 95695-5199

Cc: Mr. Kevin Vaziri, President

August 10, 2016

Re: Liability Avoidance at Woodland Healthcare

Dear Ms Childers,

Thank you for the trial of HotDog® patient warming at Woodland Healthcare. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.

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Dr. Allan Chief of Anesthesia Woodland Healthcare 1325 Cottonwood Street Woodland, CA 95695-5199

Cc: Mr. Kevin Vaziri, President

August 10, 2016

Re: Liability Avoidance at Woodland Healthcare

Dear Dr. Allan,

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Dr. Hoang Tran Chief of Orthopedics Woodland Healthcare 632 W. Gibson Road Woodland, CA 95695

Cc: Mr. Kevin Vaziri, President

August 10, 2016

Re: Liability Avoidance at Woodland Healthcare

Dear Dr. Tran,

Thank you for the trial of HotDog® patient warming at Woodland Healthcare. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%. ¹

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Ms. Kim Sivley OR Manager Woodland Healthcare 1325 Cottonwood Street Woodland, CA 95695-5199

Cc: Mr. Kevin Vaziri, President

August 10, 2016

Re: Liability Avoidance at Woodland Healthcare

Dear Ms. Sivley,

Thank you for the trial of HotDog® patient warming at Woodland Healthcare. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%. ¹

In general terms, the use of forced-air warming is antithetical during implant surgery. "Nothing that blows air should be in an operating theater, if possible," according to experts from the Centers for Disease Control and Prevention (CDC) and advisors from the Healthcare Infection Control Practices Advisory Committee. "[I]t is important," the warning continues, "not to blow air in the operating theater."

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Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

- 61. The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
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- 63. PJIs costs \$100,000-150,000 each and are not reimbursed by Medicare and many insurers.
- 64. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

PS: We're hearing that many hospitals have been told there are <u>no</u> issues with forced-air warming in total joint surgery. If this is true for you, ask the manufacturer for indemnification.

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Mr. Bill Snyder Purchasing Woodland Healthcare 1325 Cottonwood Street Woodland, CA 95695-5199

Cc: Mr. Kevin Vaziri, President

August 10, 2016

Re: Liability Avoidance at Woodland Healthcare

Dear Mr. Snyder,

Thank you for the trial of HotDog® patient warming at Woodland Healthcare. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.

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Warm regards,

Scott Augustine MD, CEO

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Ms. Melissa Barnes Woodland Healthcare 1325 Cottonwood Street Woodland, CA 95695-5199

Cc: Mr. Kevin Vaziri, President

August 10, 2016

Re: Liability Avoidance at Woodland Healthcare

Dear Ms. Barnes,

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Mr. Matthew Bailey COO and future President Indiana University Health Bloomington Hospital 601 West Second Street Bloomington, IN 47403-2317

August 10, 2016

Re: Liability Avoidance at Indiana University Health Bloomington Hospital

Dear Mr. Bailey,

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Mr. Michael Craig Chief Financial Officer Indiana University Health Bloomington Hospital 601 West Second Street Bloomington, IN 47403-2317

Cc: Mr. Matthew Bailey, COO

August 10, 2016

Re: Liability Avoidance at Indiana University Health Bloomington Hospital

Dear Mr. Craig,

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General Counsel Indiana University Health 601 West Second Street Bloomington, IN 47403-2317

Cc: Mr. Matthew Bailey, COO

August 10, 2016

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Liability Avoidance

There are now nine (9) published studies showing that the waste heat from FAW contaminates the sterile surgical field. You may know that 3M is facing nearly 500 lawsuits alleging that their Bair Hugger® FAW is causing catastrophic periprosthetic joint infections ("PJI"). These suits have been consolidated into one Federal Court and have been certified as a Multi-District Litigation. It is expected that there could be over 20,000 suits filed before this matter is resolved.

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HotDog® Patient Warming is More Effective

Warming patients during surgery is not simply an exercise to satisfy Medicare SCIP requirements. Warm surgical patients have better outcomes and fewer complications—one study showed the cost of a hypothermic patient is between \$2,500-\$7,000. You may be aware that Bair Hugger FAW has been shown in a large study to fail over 30% of the time. A failure rate that high has significant hidden costs.

The switch to HotDog warming will save between 20% and 70% off of your current FAW costs.

Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

- 81. The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
- 82. Current research suggests that 75% of these are easily avoidable by discontinuing FAW.
- 83. PJIs costs \$100,000-150,000 each and are not reimbursed by Medicare and many insurers.
- 84. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the very wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

PS: We're hearing that many hospitals have been told there are <u>no</u> issues with forced-air warming in total joint surgery. If this is true for you, ask the manufacturer for indemnification.

- 261. McGovern et al. Forced-air warming and ultra-clean ventilation do not mix. J Bone and Joint Surg-Br. 2011;93(11):1537-1544.
- 262. Centers for Disease Control and Prevention (CDC.gov) available at: https://www.cdc.gov/hicpac/pdf/mm/November%205-6%202015HICPAC-Meeting Summary Final-508.pdf
- 263. Dasari et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. Anaesthesia 2012;67:244-249.
- 264. Legg et al. Do forced air patient-warming devices disrupt unidirectional downward airflow? J Bone and Joint Surg-Br. 2012;94-B:254-6.
- 265. Belani et al. Patient warming excess heat: The effects on orthopedic operating room ventilation performance. Anesthesia & Analgesia 2013 Aug;117(2):406-11
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- 267. Scherrer M. Hygiene and room climate in the operating room. Min Invas Ther & Allied Tech 2003;12(6);293-299.
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- 271. Mahoney CB, Odom J. Maintaining intraoperative normothermia: a meta-analysis of outcomes with costs. AANA Journal 1999; 67: 155-163
- 272. Sun Z, Honar H, Sessler DI, et al. Intraoperative core temperature patterns, transfusion requirement, and hospital duration in patients warmed with forced air. Anesthesiology 2015;122:276-85
- 273. Hayashi, H; Koizumi, T; Sumita, S.; Yamakage, M. Relative clinical heat transfer effectiveness: Forced-air warming vs. Conductive fabric electric warming. ASA abstract 2015. Submitted for publication.

Ms. Cynthia Herrington Director of Risk Management Indiana University Health Bloomington Hospital P O Box 1149 Bloomington, IN 47402-1149

Cc: Mr. Matthew Bailey, COO

August 10, 2016

Re: Liability Avoidance at Indiana University Health Bloomington Hospital

Dear Ms. Herrington,

Thank you for the trial of HotDog® patient warming at Indiana University Health Bloomington Hospital. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

In general terms, the use of forced-air warming is antithetical during implant surgery. "Nothing that blows air should be in an operating theater, if possible," according to experts from the Centers for Disease Control and Prevention (CDC) and advisors from the Healthcare Infection Control Practices Advisory Committee. "[I]t is important," the warning continues, "not to blow air in the operating theater."

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Some of the suits have named the hospital and surgeon as co-defendants, although most of the suits merely cite the hospital and surgeon. You should know that 3M has been using the "learned intermediary defense" in these suits. In short, 3M argues that they had no duty to warn the patient or the public, because they provided the doctors and hospital (the "learned intermediary") with all of the warnings that were required. In my opinion, this is an attempt to shift the blame from them to you and your staff. Switching to an air-free warming technology is the best protection for your orthopedic surgery patients—and for Indiana University Health Bloomington Hospital.

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Cost savings

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Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

- 85. The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
- 86. Current research suggests that 75% of these are easily avoidable by discontinuing FAW.
- 87. PJIs costs \$100,000-150,000 each and are not reimbursed by Medicare and many insurers.
- 88. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the very wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

PS: We're hearing that many hospitals have been told there are <u>no</u> issues with forced-air warming in total joint surgery. If this is true for you, ask the manufacturer for indemnification.

- 274. McGovern et al. Forced-air warming and ultra-clean ventilation do not mix. J Bone and Joint Surg-Br. 2011;93(11):1537-1544.
- 275. Centers for Disease Control and Prevention (CDC.gov) available at: https://www.cdc.gov/hicpac/pdf/mm/November%205-6%202015HICPAC-Meeting_Summary_Final-508.pdf
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- 286. Hayashi, H; Koizumi, T; Sumita, S.; Yamakage, M. Relative clinical heat transfer effectiveness: Forced-air warming vs. Conductive fabric electric warming. ASA abstract 2015. Submitted for publication.

Chief of Anesthesia Indiana University Health Bloomington Hospital 601 West Second Street Bloomington, IN 47403-2317

Cc: Mr. Matthew Bailey, COO

August 10, 2016

Re: Liability Avoidance at Indiana University Health Bloomington Hospital

Dear Chief of Anesthesia,

Thank you for the trial of HotDog® patient warming at Indiana University Health Bloomington Hospital. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.

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Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

- 89. The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
- 90. Current research suggests that 75% of these are easily avoidable by discontinuing FAW.
- 91. PJIs costs \$100,000-150,000 each and are not reimbursed by Medicare and many insurers.
- 92. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

PS: We're hearing that many hospitals have been told there are <u>no</u> issues with forced-air warming in total joint surgery. If this is true for you, ask the manufacturer for indemnification.

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- 288. Centers for Disease Control and Prevention (CDC.gov) available at: https://www.cdc.gov/hicpac/pdf/mm/November%205-6%202015HICPAC-Meeting Summary Final-508.pdf
- 289. Dasari et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. Anaesthesia 2012;67:244-249.
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- 297. Mahoney CB, Odom J. Maintaining intraoperative normothermia: a meta-analysis of outcomes with costs. AANA Journal 1999; 67: 155-163
- 298. Sun Z, Honar H, Sessler DI, et al. Intraoperative core temperature patterns, transfusion requirement, and hospital duration in patients warmed with forced air. Anesthesiology 2015;122:276-85
- 299. Hayashi, H; Koizumi, T; Sumita, S.; Yamakage, M. Relative clinical heat transfer effectiveness: Forced-air warming vs. Conductive fabric electric warming. ASA abstract 2015. Submitted for publication.

Ms. Valynda Laird Director of Risk Management Indiana University Health Bloomington Hospital P O Box 1149 Bloomington, IN 47402-1149

Cc: Mr. Matthew Bailey, COO

August 10, 2016

Re: Liability Avoidance at Indiana University Health Bloomington Hospital

Dear Ms. Laird,

Thank you for the trial of HotDog® patient warming at Indiana University Health Bloomington Hospital. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

In general terms, the use of forced-air warming is antithetical during implant surgery. "Nothing that blows air should be in an operating theater, if possible," according to experts from the Centers for Disease Control and Prevention (CDC) and advisors from the Healthcare Infection Control Practices Advisory Committee. "[I]t is important," the warning continues, "not to blow air in the operating theater."

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HotDog is the only practical warming technology that is *more* effective than FAW. HotDog simultaneously warms from both above and below the patient, resulting in much higher warming rates.¹³

Cost savings

The switch to HotDog warming will save between 20% and 70% off of your current FAW costs.

Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

- 93. The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
- 94. Current research suggests that 75% of these are easily avoidable by discontinuing FAW.
- 95. PJIs costs \$100,000-150,000 each and are not reimbursed by Medicare and many insurers.
- 96. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the very wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

PS: We're hearing that many hospitals have been told there are <u>no</u> issues with forced-air warming in total joint surgery. If this is true for you, ask the manufacturer for indemnification.

- 300. McGovern et al. Forced-air warming and ultra-clean ventilation do not mix. J Bone and Joint Surg-Br. 2011;93(11):1537-1544.
- 301. Centers for Disease Control and Prevention (CDC.gov) available at: https://www.cdc.gov/hicpac/pdf/mm/November%205-6%202015HICPAC-Meeting_Summary_Final-508.pdf
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- 312. Hayashi, H; Koizumi, T; Sumita, S.; Yamakage, M. Relative clinical heat transfer effectiveness: Forced-air warming vs. Conductive fabric electric warming. ASA abstract 2015. Submitted for publication.

Dr. Aaron Mast Chief of Orthopedics Indiana University Health Bloomington Hospital 601 West Second Street Bloomington, IN 47403-2317

Cc: Mr. Matthew Bailey, COO

August 10, 2016

Re: Liability Avoidance at Indiana University Health Bloomington Hospital

Dear Dr. Mast,

Thank you for the trial of HotDog® patient warming at Indiana University Health Bloomington Hospital. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

In general terms, the use of forced-air warming is antithetical during implant surgery. "Nothing that blows air should be in an operating theater, if possible," according to experts from the Centers for Disease Control and Prevention (CDC) and advisors from the Healthcare Infection Control Practices Advisory Committee. "[I]t is important," the warning continues, "not to blow air in the operating theater."

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Some of the suits have named the hospital and surgeon as co-defendants, although most of the suits merely cite the hospital and surgeon. You should know that 3M has been using the "learned intermediary defense" in these suits. In short, 3M argues that they had no duty to warn the patient or the public, because they provided the doctors and hospital (the "learned intermediary") with all of the warnings that were required. In my opinion, this is an attempt to shift the blame from them to you and your staff. Switching to an air-free warming technology is the best protection for your orthopedic surgery patients—and for Indiana University Health Bloomington Hospital.

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Cost savings

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Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

- 97. The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
- 98. Current research suggests that 75% of these are easily avoidable by discontinuing FAW.
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Again I compliment you on the very wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

PS: We're hearing that many hospitals have been told there are <u>no</u> issues with forced-air warming in total joint surgery. If this is true for you, ask the manufacturer for indemnification.

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- 325. Hayashi, H; Koizumi, T; Sumita, S.; Yamakage, M. Relative clinical heat transfer effectiveness: Forced-air warming vs. Conductive fabric electric warming. ASA abstract 2015. Submitted for publication.

Ms. Ruth Ann Morris Chief Nursing Officer Indiana University Health Bloomington Hospital 601 West Second Street Bloomington, IN 47403-2317

Cc: Mr. Matthew Bailey, COO

August 10, 2016

Re: Liability Avoidance at Indiana University Health Bloomington Hospital

Dear Ms. Ruth Ann Morris,

Thank you for the trial of HotDog® patient warming at Indiana University Health Bloomington Hospital. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

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Warm regards,

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Ms. Dena Klineline OR Manager Indiana University Health Bloomington Hospital 601 West Second Street Bloomington, IN 47403-2317

Cc: Mr. Matthew Bailey, COO

August 10, 2016

Re: Liability Avoidance at Indiana University Health Bloomington Hospital

Dear Ms. Klineline,

Thank you for the trial of HotDog® patient warming at Indiana University Health Bloomington Hospital. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

In general terms, the use of forced-air warming is antithetical during implant surgery. "Nothing that blows air should be in an operating theater, if possible," according to experts from the Centers for Disease Control and Prevention (CDC) and advisors from the Healthcare Infection Control Practices Advisory Committee. "[I]t is important," the warning continues, "not to blow air in the operating theater."

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Cost savings

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Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

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- 106. Current research suggests that 75% of these are easily avoidable by discontinuing FAW.
- 107. PJIs costs \$100,000-150,000 each and are not reimbursed by Medicare and many insurers.
- 108. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the very wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

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Purchasing Manager Indiana University Health Bloomington Hospital 601 West Second Street Bloomington, IN 47403-2317

Cc: Mr. Matthew Bailey, COO

August 10, 2016

Re: Liability Avoidance at Indiana University Health Bloomington Hospital

Dear Purchasing Manager,

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Again I compliment you on the very wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

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Dr. Ken Marshall Chief Medical Officer Indiana University Health Bloomington Hospital 601 West Second Street Bloomington, IN 47403-2317

Cc: Mr. Matthew Bailey, COO

August 10, 2016

Re: Liability Avoidance at Indiana University Health Bloomington Hospital

Dear Dr. Marshall,

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Mr. Paul Hanson Executive Vice President Sanford USD Medical Center PO Box 5039 Sioux Falls, SD 57117-5039

August 10, 2016

Re: Liability Avoidance at Sanford USD Medical Center

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Ms. Merrilee Schultz Chief Financial Officer Sanford USD Medical Center PO Box 5039 Sioux Falls, SD 57117-5039

Cc: Mr. Paul Hanson, Executive Vice President

August 10, 2016

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Mr. Kim Patrick General Counsel Sanford Health 2301 East 60th St. N. Sioux Falls, SD 57104

Cc: Mr. Paul Hanson, Executive Vice President

August 10, 2016

Re: Liability Avoidance at Sanford Health

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HotDog® Patient Warming is More Effective

Warming patients during surgery is not simply an exercise to satisfy Medicare SCIP requirements. Warm surgical patients have better outcomes and fewer complications—one study showed the cost of a hypothermic patient is between \$2,500-\$7,000. You may be aware that Bair Hugger FAW has been shown in a large study to fail over 30% of the time. A failure rate that high has significant hidden costs.

HotDog is the only practical warming technology that is *more* effective than FAW. HotDog simultaneously warms from both above and below the patient, resulting in much higher warming rates.¹³

Cost savings

The switch to HotDog warming will save between 20% and 70% off of your current FAW costs.

Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

- 125. The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
- 126. Current research suggests that 75% of these are easily avoidable by discontinuing FAW.
- 127. PJIs costs \$100,000-150,000 each and are not reimbursed by Medicare and many insurers.
- 128. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

PS: We're hearing that many hospitals have been told there are <u>no</u> issues with forced-air warming in total joint surgery. If this is true for you, ask the manufacturer for indemnification.

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- 416. Hayashi, H; Koizumi, T; Sumita, S.; Yamakage, M. Relative clinical heat transfer effectiveness: Forced-air warming vs. Conductive fabric electric warming. ASA abstract 2015. Submitted for publication.

Ms Cindy Baldwin Risk Manager Sanford USD Medical Center PO Box 5039 Sioux Falls, SD 57117-5039

Cc: Mr. Paul Hanson, Executive Vice President

August 10, 2016

Re: Liability Avoidance at Sanford USD Medical Center

Dear Ms Baldwin,

Thank you for the trial of HotDog® patient warming at Sanford USD Medical Center. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

In general terms, the use of forced-air warming is antithetical during implant surgery. "Nothing that blows air should be in an operating theater, if possible," according to experts from the Centers for Disease Control and Prevention (CDC) and advisors from the Healthcare Infection Control Practices Advisory Committee. "[I]t is important," the warning continues, "not to blow air in the operating theater."

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- The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
- Current research suggests that 75% of these are easily avoidable by discontinuing FAW.
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- 132. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

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Dr. Scott Atchison Anesthesia Sanford USD Medical Center PO Box 5039 Sioux Falls, SD 57117-5039

Cc: Mr. Paul Hanson, Executive Vice President

August 10, 2016

Re: Liability Avoidance at Sanford USD Medical Center

Dear Dr. Atchison,

Thank you for the trial of HotDog® patient warming at Sanford USD Medical Center. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

In general terms, the use of forced-air warming is antithetical during implant surgery. "Nothing that blows air should be in an operating theater, if possible," according to experts from the Centers for Disease Control and Prevention (CDC) and advisors from the Healthcare Infection Control Practices Advisory Committee. "[I]t is important," the warning continues, "not to blow air in the operating theater."

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Warm regards,

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Mr. Chris Smith Chief CRNA Sanford USD Medical Center PO Box 5039 Sioux Falls, SD 57117-5039

Cc: Mr. Paul Hanson, Executive Vice President

August 10, 2016

Re: Liability Avoidance at Sanford USD Medical Center

Dear Mr. Smith,

Thank you for the trial of HotDog® patient warming at Sanford USD Medical Center. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

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Dr. Dustin Bechtold Orthopedics Sanford USD Medical Center PO Box 5039 Sioux Falls, SD 57117-5039

Cc: Mr. Paul Hanson, Executive Vice President

August 10, 2016

Re: Liability Avoidance at Sanford USD Medical Center

Dear Dr. Bechtold,

Thank you for the trial of HotDog® patient warming at Sanford USD Medical Center. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

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Chief of Surgery Sanford USD Medical Center PO Box 5039 Sioux Falls, SD 57117-5039

Cc: Mr. Paul Hanson, Executive Vice President

August 10, 2016

Re: Liability Avoidance at Sanford USD Medical Center

Dear Chief of Surgery,

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- 478. Reed M et al. Forced Air Warming Design: An Evaluation of Intake Filtration, Internal Microbial Build-Up, and Airborne-Contamination Emissions. *AANA Journal* 2013;81(4):275-280
- 479. Mahoney CB, Odom J. Maintaining intraoperative normothermia: a meta-analysis of outcomes with costs. AANA Journal 1999; 67: 155-163
- 480. Sun Z, Honar H, Sessler DI, et al. Intraoperative core temperature patterns, transfusion requirement, and hospital duration in patients warmed with forced air. Anesthesiology 2015;122:276-85
- 481. Hayashi, H; Koizumi, T; Sumita, S.; Yamakage, M. Relative clinical heat transfer effectiveness: Forced-air warming vs. Conductive fabric electric warming. ASA abstract 2015. Submitted for publication.

Mr. Stan Gartner OR Manager Sanford USD Medical Center PO Box 5039 Sioux Falls, SD 57117-5039

Cc: Mr. Paul Hanson, Executive Vice President

August 10, 2016

Re: Liability Avoidance at Sanford USD Medical Center

Dear Mr. Gartner,

Thank you for the trial of HotDog® patient warming at Sanford USD Medical Center. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

In general terms, the use of forced-air warming is antithetical during implant surgery. "Nothing that blows air should be in an operating theater, if possible," according to experts from the Centers for Disease Control and Prevention (CDC) and advisors from the Healthcare Infection Control Practices Advisory Committee. "[I]t is important," the warning continues, "not to blow air in the operating theater."

Liability Avoidance

There are now nine (9) published studies showing that the waste heat from FAW contaminates the sterile surgical field. You may know that 3M is facing nearly 500 lawsuits alleging that their Bair Hugger® FAW is causing catastrophic periprosthetic joint infections ("PJI"). These suits have been consolidated into one Federal Court and have been certified as a Multi-District Litigation. It is expected that there could be over 20,000 suits filed before this matter is resolved.

Some of the suits have named the hospital and surgeon as co-defendants, although most of the suits merely cite the hospital and surgeon. You should know that 3M has been using the "learned intermediary defense" in these suits. In short, 3M argues that they had no duty to warn the patient or the public, because they provided the doctors and hospital (the "learned intermediary") with all of the warnings that were required. In my opinion, this is an attempt to shift the blame from them to you and your staff. Switching to an air-free warming technology is the best protection for your orthopedic surgery patients—and for Sanford USD Medical Center.

HotDog® Patient Warming is More Effective

Cost savings

The switch to HotDog warming will save between 20% and 70% off of your current FAW costs.

Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

- The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
- 150. Current research suggests that 75% of these are easily avoidable by discontinuing FAW.
- 151. PJIs costs \$100,000-150,000 each and are not reimbursed by Medicare and many insurers.
- 152. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the very wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

PS: We're hearing that many hospitals have been told there are <u>no</u> issues with forced-air warming in total joint surgery. If this is true for you, ask the manufacturer for indemnification.

- 482. McGovern et al. Forced-air warming and ultra-clean ventilation do not mix. J Bone and Joint Surg-Br. 2011;93(11):1537-1544.
- 483. Centers for Disease Control and Prevention (CDC.gov) available at: https://www.cdc.gov/hicpac/pdf/mm/November%205-6%202015HICPAC-Meeting_Summary_Final-508.pdf
- 484. Dasari et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. Anaesthesia 2012;67:244-249.
- 485. Legg et al. Do forced air patient-warming devices disrupt unidirectional downward airflow? J Bone and Joint Surg-Br. 2012;94-B:254-6.
- 486. Belani et al. Patient warming excess heat: The effects on orthopedic operating room ventilation performance. Anesthesia & Analgesia 2013 Aug;117(2):406-11
- 487. Legg, AJ and Hamer AJ. Forced-air patient warming blankets disrupt unidirectional airflow. Bone and Joint Journal, March 2013 vol. 95-B no. 3 407-410
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- 492. Mahoney CB, Odom J. Maintaining intraoperative normothermia: a meta-analysis of outcomes with costs. AANA Journal 1999; 67: 155-163
- 493. Sun Z, Honar H, Sessler DI, et al. Intraoperative core temperature patterns, transfusion requirement, and hospital duration in patients warmed with forced air. Anesthesiology 2015;122:276-85
- 494. Hayashi, H; Koizumi, T; Sumita, S.; Yamakage, M. Relative clinical heat transfer effectiveness: Forced-air warming vs. Conductive fabric electric warming. ASA abstract 2015. Submitted for publication.

Ms. Deb Drietz Purchasing Sanford USD Medical Center PO Box 5039 Sioux Falls, SD 57117-5039

Cc: Mr. Paul Hanson, Executive Vice President

August 10, 2016

Re: Liability Avoidance at Sanford USD Medical Center

Dear Ms. Drietz,

Thank you for the trial of HotDog® patient warming at Sanford USD Medical Center. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

In general terms, the use of forced-air warming is antithetical during implant surgery. "Nothing that blows air should be in an operating theater, if possible," according to experts from the Centers for Disease Control and Prevention (CDC) and advisors from the Healthcare Infection Control Practices Advisory Committee. "[I]t is important," the warning continues, "not to blow air in the operating theater."

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Some of the suits have named the hospital and surgeon as co-defendants, although most of the suits merely cite the hospital and surgeon. You should know that 3M has been using the "learned intermediary defense" in these suits. In short, 3M argues that they had no duty to warn the patient or the public, because they provided the doctors and hospital (the "learned intermediary") with all of the warnings that were required. In my opinion, this is an attempt to shift the blame from them to you and your staff. Switching to an air-free warming technology is the best protection for your orthopedic surgery patients—and for Sanford USD Medical Center.

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Consider also the cost savings of avoided PJIs for a hospital doing 2,000 hip and knee replacements:

- 153. The typical PJI rate is 2% according to Medicare, which equals 40 catastrophic PJIs per year.
- 154. Current research suggests that 75% of these are easily avoidable by discontinuing FAW.
- 155. PJIs costs \$100,000-150,000 each and are not reimbursed by Medicare and many insurers.
- 156. Your decision to switch from FAW could prevent 30 of those 40 infections at a cost savings of \$3-4.5 million annually.

Again I compliment you on the very wise decision to discontinue the use of forced-air warming in orthopedic surgery. We at Augustine Temperature Management look forward to serving your patient warming needs with our HotDog system. Please contact me directly at 612-710-1277 (m) with questions or comments.

Warm regards,

Scott Augustine MD, CEO

PS: We're hearing that many hospitals have been told there are <u>no</u> issues with forced-air warming in total joint surgery. If this is true for you, ask the manufacturer for indemnification.

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- 496. Centers for Disease Control and Prevention (CDC.gov) available at: https://www.cdc.gov/hicpac/pdf/mm/November%205-6%202015HICPAC-Meeting_Summary_Final-508.pdf
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- 507. Hayashi, H; Koizumi, T; Sumita, S.; Yamakage, M. Relative clinical heat transfer effectiveness: Forced-air warming vs. Conductive fabric electric warming. ASA abstract 2015. Submitted for publication.

Ms. Sarah Burdick Purchasing Sanford USD Medical Center PO Box 5039 Sioux Falls, SD 57117-5039

Cc: Mr. Paul Hanson, Executive Vice President

August 10, 2016

Re: Liability Avoidance at Sanford USD Medical Center

Dear Ms. Burdick,

Thank you for the trial of HotDog® patient warming at Sanford USD Medical Center. We applaud your wise decision to discontinue forced-air warming ("FAW") in orthopedic surgery. As you know, published and unpublished reports indicate that other hospitals that have made this switch have seen their joint replacement infection rates drop by approximately 75%.¹

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Scott Augustine MD, CEO

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- 509. Centers for Disease Control and Prevention (CDC.gov) available at: https://www.cdc.gov/hicpac/pdf/mm/November%205-6%202015HICPAC-Meeting_Summary_Final-508.pdf
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- 518. Mahoney CB, Odom J. Maintaining intraoperative normothermia: a meta-analysis of outcomes with costs. AANA Journal 1999; 67: 155-163
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- 520. Hayashi, H; Koizumi, T; Sumita, S.; Yamakage, M. Relative clinical heat transfer effectiveness: Forced-air warming vs. Conductive fabric electric warming. ASA abstract 2015. Submitted for publication

EXHIBIT L



April 15, 2015

Evan C. Holden Greenberg Traurig, LLP Terminus 200 3333 Piedmont Road, NE Suite 2500 Atlanta, GA 30305

Re: Tommy Walton V. 3M Company, Arizant Healthcare Inc., and Robert Prestera USDC—Southern District of Texas, Docket No. 4:13-cv-1164.

Dear Mr. Holden,

I am attorney for Dr. Scott Augustine, and I am writing on his behalf regarding the subpoena duces tecum served by your client in the above-captioned matter. Please consider this communication to be an objection to your client's demands as well as assertions of privilege and protection as provided for by FRCP 45. Such objections and assertions include the following.

General Objections

The following General Objections apply to Requests 1-15 generally and to each Request specifically.

- 1. The demands are overly broad, vague and ambiguous.
- 2. The demands are unreasonable and oppressive.
- 3. The demands require disclosure of confidential and trade-secret documents and information.
- 4. The demands require disclosure of documents and information that is not relevant to the litigation under Rule 26.
- 5. The demands require disclosure of documents and information available from the discovering party itself or from public sources.
- 6. The demands require disclosure of documents and information the production of which would be unduly burdensome and expensive.
- 7. Although the subpoena was served personally on Dr. Augustine, the document requests include documents belonging to Augustine Biomedical (as defined broadly by the Definitions). Having not been served, the independent legal entities therein defined have no obligation to respond.
- 8. The demands require disclosure of documents and information that are privileged of otherwise protected from disclosure. To fully comply with FRCP 45(e)(2)(A) at this point would itself be unduly burdensome and expensive, but further elaboration will occur when and if required.

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Specific Objections

The following Specific Objections are intended to be an elaboration of the General Objections stated above, but do not limit the application of the General Objections to any of the individual Requests.

- 1. Request No. 1—To the extent such documents, if any, exist, they would be protected from disclosure by attorney-client privilege and as attorney work product.
- 2. Request No. 2-- To the extent such documents, if any, exist, they would be protected from disclosure by attorney-client privilege and as attorney work product.
- 3. Request No. 3-- General Objections 1-7, above, are specifically asserted regarding this Request.
- 4. Request No. 4—To the extent such documents, if any, exist, General Objections 1-7, above, are specifically asserted regarding this Request.
- 5. Request No. 5-- To the extent such documents, if any, exist, General Objections 1, 2 and 4-7, above, are specifically asserted regarding this Request.
- 6. Request No. 6-- To the extent such documents, if any, exist, General Objections 1, 2 and 4-7, above, are specifically asserted regarding this Request.
- 7. Request No. 7-- To the extent such documents, if any, exist, General Objections 1, 2 and 4-7, above, are specifically asserted regarding this Request.
- 8. Request No. 8-- To the extent such documents, if any, exist, General Objections 1, 2 and 4-7, above, are specifically asserted regarding this Request.
- 9. Request No. 9— To the extent such documents, if any, exist, General Objections 1, 2 and 4-7, above, are specifically asserted regarding this Request.
- 10. Request No. 10-- To the extent such documents, if any, exist, General Objections 1, 2 and 4-8, above, are specifically asserted regarding this Request.
- 11. Request No. 11-- To the extent such documents, if any, exist, General Objections 1-8, above, are specifically asserted regarding this Request.
- 12. Request No. 12-- To the extent such documents, if any, exist, General Objections 1, 2 and 4-7, above, are specifically asserted regarding this Request.
- 13. Request No. 13-- To the extent such documents, if any, exist, they would be protected from disclosure by attorney-client privilege and as attorney work product.
- 14. Request No. 14-- No further elaboration.
- 15. Request No. 15-- No further elaboration.

I look forward to your proposals for dealing with these objections.

Dr. Augustine can be available for deposition on May 6, 2015 as demanded, provided that you offer assurances that the scope of inquiry will be limited to subjects germane to the litigation. Dr. Augustine's employer, Augustine Temperature Management ("ATM"), manufactures HotDog patient warming-- a significant competitor to your client's Bair Hugger patient warming.

Obviously, it would be inappropriate for your client to use the discovery process to obtain competitive information from Dr. Augustine. Please provide assurances, therefore, that your questions for Dr. Augustine will relate only to the alleged risks of forced-air warming and that there will be no questions regarding ATM's sales, marketing, promotion, manufacturing, research & development, finances, business plans, business relationships, or similarly irrelevant topics.

If your client is unwilling to offer such assurances, please advise me promptly so that I can take appropriate actions.

As a courtesy, I have copied your opposing counsel on this correspondence.

Sincerely,

J. Randall Benham General Counsel

Augustine Biomedical + Design LLC

6581 City West Parkway Eden Prairie, MN 55344

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct correct copy of the documents attached hereto has been served on the following counsel of record via first class mail on April 15, 2015.

David W. Hodges Gabriel Assaad Kennedy Hodges, LLP 711 W. Alabama Street Houston, TX 77006 Kyle Farrar Mark Bankston Farrar & Ball, LLP 1010 Lamar Street, Suite 1600 Houston, TX 77002

Evan C. Holden Greenberg Traurig, LLP Terminus 200 3333 Piedmont Road, NE Suite 2500 Atlanta, GA 30305

Wan Schaefer 4/15/15

EXHIBIT M

UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

TOMMY WALTON,

DMinn No. 15-mc-64 JNE/FLN

DTx No. 13-cv-01164

Plaintiff

AFFIDAVIT OF

J. RANDALL BENHAM

V.

3M COMPANY; ARIZANT HEATHCARE, INC.; AND ROBERT PRESTERA

Defendants.

- 1. My name is J. Randall Benham, and I am an attorney licensed to practice in Minnesota's state and federal courts. I am general counsel of Augustine Biomedical + Design LLC ("ABD") and perform a similar function for other business entities affiliated with ABD, including Augustine Temperature Management LLC and the other entities subject to Defendants' Motion to Compel. Dr. Scott Augustine is Chief Executive Officer of each of these entities (Although I am unaware of any entity called "Augustine Team LLC.").
- 2. The facts contained herein are within my personal knowledge (except when stated as being on information and belief) and are true and correct.
- 3. On or about April 30, 2015 and therafter, Dr. Augustine, ABD and various entities affiliated with ABD were served with third-party discover documents by Defendants.

The documents demanded that Dr. Augustine appear for deposition on May 28, 2015, and that documents be produced by Dr. Augustine and various entities at the time of Dr. Augustine's deposition.

- 4. I objected to the document requests on behalf of Dr. Augustine and the ABD-affiliated companie within the time specified by the Federal Rules. As the only person in the legal department, I also began taking the preliminary steps to comply with those portions of the document requests that I believed would ultimately be sustained.
- Almost immediately, however, counsel for Plaintiffs and Defendants began to squabble about the date of Dr. Augustine's deposition.
- 6. The parties apparently were unable to agree to deposition dates within the range of dates on which Dr. Augustine was available, and the matter essentially went quiet for several weeks. Having many other duties, I suspended my efforts to locate documents legitimately responsive to the subpoena until such time as the parties could reach an agreement as to the date of Dr. Augustine's deposition—presumably the date on which production would occur.
- 7. The squabbling between the parties has continued unabated—with Defendants' counsel apparently scheduling a second day of deposition for Dr. Augustine on a day that Plaintiff's counsel had specifically excluded.
- 8. During the initial discussions, I objected to counsel for both parties regarding having Dr. Augustine's deposition taken on two separate days by identical counsel in two different matters—the *Walton* and *Johnson* cases. Because his testimony would cover the same subjects on both cases, I requested that the first deposition simply be used

CASE 0.55 m 0.00064 NEPEN Document 26 led 100/29/18 acre age 306/24 in both cases. Counsel for Defendants refused. Given that a petition has now been filed for pre-trial consolidation of the 16+ pending cases with the Panel for Multi-District Litigation, I hope that such abuse of Dr. Augustine and other non-party witnesses can be avoided. According to the logic of Defendants' counsel, Dr. Augustine is subject to deposition in all 16 of the existing cases—and potentially in however many others are filed in the future.

- 9. By email on August 17, attached hereto, I informed Defendants counsel of the status of production. By that email I also requested clarification of one request (No. 9) and informally requested a narrowing of another (No. 11).
- 10. On August 18, I received an email from Defendants' counsel demanding that documents be produced by August 25. While the deadline seemed arbitrary, given that Dr. Augustine's deposition was scheduled for October 13, I nevertheless began working to meet the deadline.
- 11. Defendants' counsel did not respond to my requests for clarification and narrowing, but only filed this Motion to Compel.
- 12. I was able to meet the August 25 deadline regarding Requests Nos. 2, 3, 4, 7, 8, and 10. (Electronic production commenced on August 25, but due to the limitations of Defendants' counsel's FTP site, was not completed until August 26.) I was unable to identify any documents responsive to Requests Nos. 5 and 6. I await a response from Defendants' counsel regarding my inquiry regarding Request No. 9 and my request that the scope of Request No. 11 be narrowed.

- 13. I have refused on behalf of my client to produce documents only in response to Requests Nos. 1 and 12—both on the basis of privilege. As was represented to Southern District of Texas Judge Hoyt in Walton, Plaintiff and his counsel "have had no contact or communications with Dr. Augustine relative to this case..." other than a phone call than was described to the Texas court. There have been no such communications regarding Johnson at all. As regards to attorney-client communications unrelated to Walton or Johnson, to the best of my knowledge, there are no responsive communications to, from, or in the possession of Dr. Augustine.
- 14. On behalf of Dr. Augustine and the ABD-affiliated companies, I established an attorney-client relationship with the Kennedy Hodges firm several years ago. While I cannot be precise about the date the relationship was created, I do not quarrel with the July 6, 2009 date offered by Kennedy Hodges in the *Walton* case. The firm advised me on a variety of legal matters, including product liability. All such communications involved only myself (acting a general counsel) and Kennedy Hodges's attorneys.
 - 15. Defendants' Memorandum makes much of the fact that I was reluctant to schedule a "meet and confer." While there have been no face-to-face meetings or telephone conversations, that does not mean that I have been unwilling or uncooperative in this matter. In fact, I responded to each communication from Defendants' counsel respectfully and promptly. Moreover, other than regarding those items subject to the attorney-client privilege, I produced documents on the date demanded by Defendants.

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16. That said, I cannot deny that I elected to communicate with Defendants' counsel in writing rather than orally. My experience is that oral communications between counsel sometimes become affidavits that fail to capture the oral communications accurately. Written communications are much more precise and less open to mischaracterization.

FURTHER AFFIANT SAYETH NOT

J. Randall Benham

CASEU 1.5544000064194EDFEN DO6c4AFeAt 261eHiAU 109/29/1Baquade605P74

Subject: Re: Walton v. 3M - Deposition of Dr. Augustine

Date: Monday, August 17, 2015 at 4:01:06 PM Central Daylight Time

From: Randy Benham <rbenham@augbiomed.com>

To: JacxsensC@gtlaw.com <JacxsensC@gtlaw.com>, holdene@gtlaw.com <holdene@gtlaw.com>

CC: CohenL@gtlaw.com <CohenL@gtlaw.com>, OstfeldG@gtlaw.com <OstfeldG@gtlaw.com>, Gabriel

Assaad <gassaad@kennedyhodges.com>, David Hodges <dhodges@kennedyhodges.com>

BCC: Randy Benham <rbenham@augbiomed.com>

Christiana,

As our previous communications have all been copied to all counsel, I thought it appropriate to cop this one as well.

I was able to spend some time this afternoon reviewing your document requests my initial objections, and my follow-up that provided greater specificity. Although all of my objections remain valid, I am able to provide you with a bit more information about my clients' responses to your demands. Although I have not yet commenced a physical review of our files I am relatively confident of the following:

- 1. Augustine Biomedical + Design will have no documents responsive to your demands.
- 2. Hot Dog USA, having not existed for some years, will have no documents responsive to your demands.
- 3. Dr. Augstine will have no documents in his personal capacity, but only in his capacity as CEO of Augustine Temperature Management LC (ATM).

 4. To the extent any documents exist and have not be objected to, they
- are likely to be documents belonging to ATM.

 The multiple sets of slightly varying document requests create a great opportunity for confusion. I will refer, therefore, to those attached to your letter of July 23. Without waiving my earlier objections and attempting to speak plainly rather than in legalese, my positions are as follows:
- 1. Req. 1— To the extent any such documents exist, they were obtained by, were considered by and are in the possession of ATM's legal counsel. Mreover, they are documents that can be obtained through the PACER sstem. I do not believe that production is required.
- 2. Req.2— All such documents are subject to the attorney-client privilege and other legal privileges.
- 3. Req. 3— To the extent such documents exist, they will be produced.
- 4. Req. 4— To the best of my current knowledge, no such documents exist. Review will continue.
- 5. Reg. 5- To the extent such documents exist, they will be produced.
- Req. 6— To the extent such documents exist, they will be produced.
- 7. Req. 7--To the best of my current knowlege, no such documents exist.

Review will continue.

- 8. Req. 8— While it is unlikely that such ocuments exist, I will conduct a review.
- 9. Reg. 9— To the extent sch documents exist, they will be produced.
- 10. Req. 10— I have no been able to locate the letter to which you refer. Would you please provide a copy?
- 11. Req. 11— To the extent such documents exist, they will be produced.
- 12. Req. 12— This is a bit broad. Are you really asking for every email every written by anyone in the company regarding forced air warming? That is a bit absurd.
- 13. Req. 13-See Req. No 1.
- 14. Reg. 14- NA
- 15. Req. 15— I am uncertain as to whether or not this exists. I will look.

As noted, my physical search for these documets has not yet begun. Given my other responsibilities, I expect that it will take a couple of weeks. If the effort and/or copying costs become too burdensome, I will contact you regarding reimbursement.

I am also concerned about the double-scheduling of Dr. Augustine's deposition on October 13 (the day I offered) and October 15 (a day I did not offer). Given that your opposing counsel has stated that they are not available on October 15, perhaps the issue is moot. Nevertheless, I have noticed via PACER that other cases have been filed. Surely you do not expect Dr. Augustine to make himself available for deposition in each case. Please let me know how you and opposing counsel propose to deal with this issue.

I hope that this email makes the telephone conference requested by Mr. Holden unnecessary.

Randy

J. Randall Benham

General Counsel Augustine Temperature Management LLC 6581 City West Parkway Eden Prairie, MN 55344

EXHIBIT N

Privilege Log

Identification:

- S. Augustine, CEO Augustine Temperature Management
- B. Augustine, President, Augustine Temperature Management
- R. Benham, General Counsel Augustine Temperature Management
- D. Hodges, attorney
- G. Assaad, attorney
- J. Neuman, attorney
- D. Grewe, executive employee of Augustine Temperature Management

	Document Type	Date of Document	Author(s)	Recipient(s)	Persons Copied	Subject Matter	Category of Privilege
1	Email series	2/1/13	S. Augustine, D. Hodges	D. Hodges, S. Augustine	R. Benham	Litigation	Attorney/Client, work product
2	Email series	4/8/13	R. Benham, D. Hodges	R. Benham, D. Hodges	S. Augustine	Litigation	Attorney/Client, work product
3	Email series	4/29/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation	Attorney/Client, work product
4	Email series	4/30/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation	Attorney/Client, work product
5	Email series	5/1/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation	Attorney/Client, work product
6	Email series	5/15/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation	Attorney/Client, work product
7	Email series	5/21/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation	Attorney/Client, work product
8	Email series	5/22/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation	Attorney/Client, work product
9	Email series	5/28/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation	Attorney/Client, work product
10	Email series	5/29/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation	Attorney/Client, work product

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11	Email series	5/31/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine	Litigation	Attorney/Client, work product
12	Email series	6/6/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine, B. Augustine	Litigation	Attorney/Client, work product
13	Email series	6/7/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, S. Augustine, B. Augustine	Litigation	Attorney/Client, work product
14	Email series	6/27/13	R. Benham, D. Hodges	R. Benham, D. Hodges	S. Augustine, D. Grewe	Litigation	Attorney/Client, work product
15	Email series	7/18/13	R. Benham, D. Hodges	R. Benham, D. Hodges	S. Augustine, D. Grewe, G. Assaad	Litigation	Attorney/Client, work product
16	Email series	8/1/13	R. Benham, D. Hodges	R. Benham, D. Hodges	S. Augustine, D. Grewe, G. Assaad	Litigation	Attorney/Client, work product
17	Email series	9/23/13	R. Benham, D. Hodges, G. Assaad	R. Benham, D. Hodges, G. Assaad	S. Augustine, B. Augustine	Litigation	Attorney/Client, work product
18	Email series	11/20/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, J. Neuman, S. Augustine	Litigation	Attorney/Client, work product
19	Email series	12/3/13	R. Benham, D. Hodges	R. Benham, D. Hodges	G. Assaad, J. Neuman, S. Augustine	Litigation	Attorney/Client, work product
20	Email series	2/6/14	R. Benham, D. Hodges, G. Assaad	R. Benham, D. Hodges, G. Assaad	S. Augustine	Litigation	Attorney/Client, work product
21	Email series	5/14/14	R. Benham, D. Hodges, G. Assaad	R. Benham, D. Hodges, G. Assaad	S. Augustine	Litigation	Attorney/Client, work product
22	Email series	1/26/15	G. Assaad, R. Benham, D. Hodges	G. Assaad, R. Benham, D. Hodges	S. Augustine	Litigation	Attorney/Client, work product

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23	Email series	2/9/15	G. Assaad, R. Benham	G. Assaad, R. Benham	D. Hodges, S. Augustine	Litigation	Attorney/Client, work product

EXHIBIT O

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Newsletter to the employees and sales force behind HotDog Patient Warming. April 23, 2013: Litigation - ECRI - StopSurgicalInfections.org



Dear <<First Name>>,

As you should know by now, 3M/Bair Hugger has been sued for allegedly causing a deep-joint infection in a surgical patient from Houston.

The purpose of this newsletter is to further explain the implications of the lawsuit and why it will help HotDog patient warming.

THE FIRST OF MANY—POSSIBLY THOUSANDS

3M has assured customers that there is absolutely no joint infection risk from Bair Hugger, but we believe its "failure to warn" has exposed hundreds of thousands of surgical patients to needless risk—and created massive liability for the company.

In the US alone, there are over 12,000 catastrophic deep joint infections after total joint replacement surgery per year. These patients usually survive, but are frequently permanently disabled, with 12% describing their post-infection life as "worse than death." Of course, not all will sue, but the Houston case has broken the ice. Others—maybe thousands of others—could follow.

Simple math shows how big the risk has become: multiply 12,000 infected patients per year times a 6-year statute of limitations and the total number of possible plaintiffs is 72,000. These will be at least \$1,000,000 rewards, so the total liability risk for 3M is as high as \$72 billion!

Because of the astronomical reward potential, other lawyers are jumping on this bandwagon. Take a look, for example, at http://www.faris-faris.com/bair-hugger/ and http://www.yourlawyer.com. Pretty soon, nearly every personal injury lawyer in the country could be trolling for cases...3M will have its hands full.

ONE OF 3M's DEFENSES? BLAME THE CUSTOMER

UPDATE: 3M files answer...claims it <u>adequately warned</u> <u>doctors</u> of the risks of Bair Hugger. In its Answer to the Complaint, filed April 15, 2013, 3M denied liability. Among its defenses were the following:

- 3M's duty was discharged because it <u>adequately</u> warned the Plaintiff's doctors of any risks of infection.
- Plaintiff was <u>informed of the infection risks</u> and consented to the surgery anyway.





ECRI Guidance Expresses "Concern" About FAW in Implant Surgery

The April issue of Health
Devices contains guidance from
ECRI Institute regarding the
use of forced-air warming in
surgery. ECRI is an
independent scientific
organization that advises its
members regarding medical
devices, drugs and procedures.

After reviewing multiple published, peer-reviewed articles addressing the consequences of the convection currents created by the waste heat produced by forced-air devices, ECRI stated:

"The disruption of air-flow patterns is particularly worrisome in laminar-flow and ultraclean ORs, in which a wide variety of implant surgeries are performed."

"This is especially concerning during orthopedic surgeries because contamination of the surgical site may present a greater risk of developing a PJI (peri-prosthetic joint infection), which is harder to treat and resolve than would be the case with SSIs (surgical site infections) in general."

ECRI's bright orange headline in the middle of the first page of the article was especially interesting.

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The research proves irrefutably that FAW contaminates the sterile field, but despite that evidence, healthcare is predictably slow to adapt. The lawsuit is putting the subject under the microscope and accelerating change, especially since 3M is deflecting blame on the customer. If FAW is considered unsafe in ultra clean surgery, air-free HotDog warming is the only practical and effective alternative to forced-air approved for use in the US today.

SOME HOSPITALS ARE ALREADY TAKING ACTION

The buzz is palpable. I hope you can feel it. We are doing a massive email campaign to make sure every healthcare provider in America knows the risks of FAW.

The direct mail campaign has had unprecedented open-rates, and we are experiencing record web-traffic. There is a word-of-mouth, viral element to this.

Most significantly, some hospitals have already kicked forced-air out of orthopedics, citing the recent research and litigation as reasons for change. One hospital has committed to buy HotDog systems without first trialing the product. These events should significantly decrease the sales cycle time and improve your success rate. Now's the time to press the pedal to the metal...let's go!

Warm regards, Brent Augustine FORCED-AIR WARMING MAY DISTURB AIR PATTERNS IN THE OPERATING ROOM

ECRI declined, however, to advise hospitals to discontinue using forced-air warming in all surgeries, stating the "currently available evidence" is insufficient to require such action. <u>Click here to view the</u> full press release.



We created a website called StopSurgicalInfections.org as a source of information about SSIs in general and peri-prosthetic joint infections (PJI's) in particular. It's underwritten by ATM and other healthcare-related organizations and will continually be updated with relevant information. There is currently a great explanation of PJIs at this link.

This will be a great resource; your healthcare contacts would find this information very educational.

Past topics: HotDog Herald April Edition Upcoming Topics: New Materials!

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